FEDERAL REGISTER

Vol. 86 Tuesday

No. 218 November 16, 2021

Pages 63307–64054

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.federalregister.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.govinfo.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $860 plus postage, or $929, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 86 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

The Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: *https://www.gpo.gov/frsubs.*

Contents

Federal Register

Vol. 86, No. 218

Tuesday, November 16, 2021

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

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

5 CFR
2638.....63307

7 CFR
1767.....63308

10 CFR

Proposed Rules:
429.....63318
431.....63318

14 CFR
39.....63308
97 (2 documents) 63311, 63312

Proposed Rules:
39 (2 documents) 63319, 63322

15 CFR
1500.....63315

40 CFR
52.....63315
81.....63315

42 CFR
412.....63458
416.....63458
419.....63458
512.....63458

45 CFR
180.....63458

49 CFR

Proposed Rules:
831.....63324

50 CFR
17.....64000

Rules and Regulations

Federal Register
Vol. 86, No. 218
Tuesday, November 16, 2021

OFFICE OF GOVERNMENT ETHICS

5 CFR Part 2638

RIN 3209–AA63

Executive Branch Ethics Program; Technical Correction

AGENCY: Office of Government Ethics.

ACTION: Final rule; technical correction.

SUMMARY: The Office of Government Ethics (OGE) is issuing a technical correction to the executive branch ethics program regulation that describes OGE's written guidance, following the inadvertent removal of certain paragraphs in the regulation that occurred when it was revised in August 2020.

DATES: This final rule is effective November 16, 2021.

FOR FURTHER INFORMATION CONTACT: Patrick J. Lightfoot, Associate Counsel, or Margaret Dylus-Yukins, Assistant Counsel; Telephone: 202–482–9300.

SUPPLEMENTARY INFORMATION:

I. Background

On August 20, 2020, the U.S. Office of Government Ethics (OGE) issued new regulations at 5 CFR part 2611, which set forth processes and procedures for OGE's issuance of guidance documents as required by Executive Order 13891, ''Promoting the Rule of Law Through Improved Agency Guidance Documents'' (October 9, 2019). 85 FR 51301 (August 20, 2020). In that same August 2020 rulemaking, OGE made a technical modification to 5 CFR 2638.208 ''to replace the term 'guidance documents' with the phrase 'written guidance' in order to reduce any potential confusion'' with the new 5 CFR part 2611 regulation in which ''guidance document'' had become a specific term of art. *Id.* The regulations at 5 CFR part 2611 were later removed pursuant to Executive Order 13992, ''Revocation of Certain Executive Orders Concerning Federal Regulation'' (January 20, 2021). *See* 86 FR 25801 (May 11, 2021).

Although the intent of this technical change was to replace only that phrasing in 5 CFR 2638.208, OGE's instructions to the **Federal Register** were unclear, and resulted in the inadvertent deletion of paragraphs (a), (b), and (c) in 5 CFR 2638.208. To correct this error, OGE is issuing this technical rulemaking to add paragraphs (a), (b), and (c) back into 5 CFR 2638.208 as they existed before the August 20, 2020, amendments. OGE has made no substantive change to the text of these paragraphs, which will once again read as they did when 5 CFR part 2638 was updated in 2016. *See* 81 FR 76271 (November 2, 2016).

II. Matters of Regulatory Procedure

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(b)(3)(A), as Director of the Office of Government Ethics, the notice and comment procedures are being waived because these amendments concern matters of agency organization, procedure and practice.

Regulatory Flexibility Act

As the Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this final rule would not have a significant economic impact on a substantial number of small entities because it primarily affects current Federal executive branch employees.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this regulation does not contain information collection requirements that require approval of the Office of Management and Budget.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 5, subchapter II), this final rule would not significantly or uniquely affect small governments and will not result in increased expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (as adjusted for inflation) in any one year.

Executive Order 13563 and Executive Order 12866

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select the regulatory approaches that maximize net benefits (including economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. In promulgating this rulemaking, OGE has adhered to the regulatory philosophy and the applicable principles of regulation set forth in Executive Orders 12866 and 13563. The rule has not been reviewed by the Office of Management and Budget because it is not a significant regulatory action for the purposes of Executive Order 12866.

Executive Order 12988

As Director of the Office of Government Ethics, I have reviewed this rule in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

Executive Order 13175

The Office of Government Ethics has evaluated this final rule under the criteria set forth in E.O. 13175 and determined that tribal consultation is not required as this final rule has no 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.

List of Subjects in 5 CFR Part 2638

Administrative practice and procedure, Conflict of interests, Government employees, Reporting and recordkeeping requirements.

Approved: November 9, 2021.

Emory Rounds,

Director, U.S. Office of Government Ethics.

For the reasons stated in the preamble, the U.S. Office of Government Ethics amends 5 CFR part 2638 by making the following technical correction:

PART 2638—EXECUTIVE BRANCH ETHICS PROGRAM

■ 1. The authority citation for part 2638 continues to read as follows:

Authority: 5 U.S.C. App. 101–505; E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

■ 2. Revise § 2638.208 to read as follows:

§ 2638.208 Written guidance on the executive branch ethics program.

This section describes several means by which the Office of Government Ethics provides agencies, employees, and the public with written guidance regarding its legal interpretations, program requirements, and educational offerings. Normally, written guidance is published on the official website of the Office of Government Ethics, *www.oge.gov.*

(a) *Legal advisories.* The Office of Government Ethics issues legal advisories, which are memoranda regarding the interpretation of government ethics laws and regulations. They are intended primarily to provide education and notice to executive branch ethics officials; prospective, current, and former executive branch employees; and individuals who interact with the executive branch.

(b) *Program advisories.* The Office of Government Ethics issues program advisories, which are memoranda regarding the requirements or procedures applicable to the executive branch ethics program and individual agency ethics programs. They are intended primarily to instruct agencies on uniform procedures for the executive branch ethics program.

(c) *Informal advisory opinions.* Upon request or upon its own initiative, the Office of Government Ethics issues informal advisory opinions. Informal advisory opinions address subjects that in the opinion of the Director do not meet the criteria for issuance of formal advisory opinions. They are intended primarily to provide guidance to individuals and illustrate the application of government ethics laws and regulations to specific circumstances.

[FR Doc. 2021–24878 Filed 11–15–21; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1767

[Docket No. RUS–21–ELECTRIC–0019]

RIN 0572–AC53

Streamlining Electric Program Procedures; Correction

AGENCY: Rural Utilities Service, Department of Agriculture (USDA).

ACTION: Final rule; correcting amendment.

SUMMARY: On July 9, 2021, Rural Development's Rural Utilities Service referred to as ''the Agency'' or ''Agency'' published a document to streamline its procedures for the Electric Program borrowers, including its loan application requirements, approval of construction work plans, contract bidding procedures, contact approval procedures, system operation and maintenance reviews, long-range engineering plans and system design procedures. That document inadvertently published the incorrect accounting information. This document corrects the final regulations.

DATES: Effective November 16, 2021.

FOR FURTHER INFORMATION CONTACT: For information specific to this notice contact Michele Brooks, Director, Regulations Management, Rural Development Innovation Center—Regulations Management, USDA, 1400 Independence Avenue SW, STOP 1522, Room 4266, South Building, Washington, DC 20250–1522. Telephone: (202) 690–1078. Email *michele.brooks@usda.gov.*

SUPPLEMENTARY INFORMATION: The Rural Development's Rural Utilities Service is issuing a correction to the final rule that published July 9, 2021, at 86 FR 36199. In that rule, an inadvertent error provided the incorrect information in the Special Equipment section of part 119 § 1767.41. This correcting amendment provides the proper information.

List of Subjects in 7 CFR Part 1767

Electric power, Loan programs—energy, Rural areas, Uniform System of Accounts.

For the reasons stated in the preamble, the Rural Utilities Service corrects 7 CFR part 1767 with the following correcting amendment:

PART 1767—ACCOUNTING REQUIREMENTS FOR RUS ELECTRIC BORROWERS

■ 1. The authority citation for part 1767 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.,* 1921 *et seq.,* 6941 *et seq.*

■ 2. In § 1767.41, amend entry 119 by revising entry 3 to read as follows:

§ 1767.41 Accounting methods and procedures required of all RUS borrowers.

* * * * *

119 Special Equipment

* * * * *

■ 3. Meters, Meter Sockets, current and potential transformers, and other metering equipment recorded in Account 370, Meters.

* * * * *

Christopher A. McLean,

Acting Administrator, Rural Utilities Service, U.S. Department of Agriculture.

[FR Doc. 2021–24874 Filed 11–15–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0602; Project Identifier 2019–CE–022–AD; Amendment 39–21776; AD 2021–22–03]

RIN 2120–AA64

Airworthiness Directives; Diamond Aircraft Industries GmbH Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Diamond Aircraft Industries GmbH Model DA 42, DA 42 NG, and DA 42 M–NG airplanes. This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as failure of the nose landing gear (NLG) actuator attachment lever and detachment from the NLG leg. This AD requires repetitively inspecting the NLG actuator attachment lever for cracks and damage and taking any necessary corrective actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 21, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 21, 2021.

ADDRESSES: For service information identified in this final rule, contact Diamond Aircraft Industries GmbH, N.A. Otto-Straße 5, A–2700 Wiener Neustadt, Austria; phone: +43 2622 26700; fax: +43 2622 26780; email: *office@diamond-air.at;* website: *https://www.diamondaircraft.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0602.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0602; 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 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.

FOR FURTHER INFORMATION CONTACT: Penelope Trease, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 26805 E 68th Avenue, Denver, CO 80249; phone: (303) 342–1094; email: *penelope.trease@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 all Diamond Aircraft Industries GmbH Model DA 42, DA 42 NG, and DA 42 M–NG airplanes. The NPRM published in the **Federal Register** on August 3, 2021 (86 FR 41786). The NPRM was prompted by MCAI originated by the European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union. EASA issued AD 2019–0066, dated March 27, 2019 (referred to after this as ''the MCAI''), to correct an unsafe condition for Diamond Aircraft Industries GmbH (Austria) and Diamond Aircraft Industries Inc. (Canada) Model DA 42, DA 42 M, DA 42 NG, and DA 42 M–NG airplanes. The MCAI states:

> An occurrence was reported of a failed NLG actuator attachment lever, resulting in disconnection from the NLG leg. When the landing gear (LG) was retracted, the NLG actuator interfered with the rudder control rods, forcing the rudder into left-hand deflection. After lowering the LG, full rudder control was restored. The investigation results showed that the actuator lever failed due to a crack that had developed over a longer time period.
>
> This condition, if not detected and corrected, could lead to restricted rudder travel in LG retracted configuration, possibly resulting in reduced control of the aeroplane.
>
> To address this potential unsafe condition, [Diamond Aircraft Industries] DAI issued the applicable [mandatory service bulletin] MSB, providing instructions to inspect the affected part.
>
> For the reason described above, this [EASA] AD requires repetitive inspections of the NLG leg actuator attachment lever and, depending on findings, replacement of the NLG leg.

You may examine the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0602.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

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 and service information referenced above. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. This AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Diamond Aircraft Mandatory Service Bulletin MSB 42–136/1 and MSB 42NG–078, dated January 24, 2019 (issued as one document) published with Diamond Aircraft Work Instruction WI–MSB 42–136 and WI–MSB 42NG–078, Revision 1, dated January 24, 2019 (issued as one document) attached. The service information contains procedures for repetitively inspecting the NLG actuator attachment lever and replacing the NLG leg assembly as necessary. 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 **ADDRESSES**.

Differences Between This AD and the MCAI

The MCAI applies to Model DA 42, DA 42 M, DA 42 NG, and DA 42 M–NG airplanes. This AD does not apply to the Model DA 42 M airplane because it does not have an FAA type certificate.

Costs of Compliance

The FAA estimates that this AD affects 40 airplanes of U.S. registry. The FAA also estimates it will take about 1 work-hour per airplane to comply with the inspection required by this AD and no parts would be necessary. The average labor rate is $85 per work-hour.

Based on these figures, the FAA estimates the inspection cost of this AD on U.S. operators to be $3,400 or $85 per airplane.

In addition, the FAA estimates that any necessary replacement actions will take 6 work-hours and require parts costing $1,500, for a cost of $2,010 per airplane. The FAA has no way of determining the number of airplanes that may need these actions.

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:

2021–22–03 Diamond Aircraft Industries GmbH: Amendment 39–21776; Docket No. FAA–2021–0602; Project Identifier 2019–CE–022–AD.

(a) Effective Date

This airworthiness directive (AD) is effective December 21, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Diamond Aircraft Industries GmbH Model DA 42, DA 42 NG, and DA 42 M–NG airplanes, all serial numbers, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 3221, Nose/Tail Landing Gear Attach Section.

(e) Unsafe Condition

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and address an unsafe condition on an aviation product. The MCAI describes the unsafe condition as failure of the nose landing gear (NLG) actuator attachment lever and detachment from the NLG leg. The FAA is issuing this AD to detect and correct cracks in the NLG actuator attachment lever, which could result in restricted rudder travel with the NLG retracted and reduced airplane control.

(f) Compliance

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

(g) Definition of Airworthy Part

For the purposes of this AD, an airworthy part is an NLG leg assembly that has accumulated 1,800 or fewer hours time-in-service (TIS) since first installation on an airplane or that has passed the inspection (no cracks and no damage) required by paragraph (h)(1) of this AD.

(h) Required Actions

(1) Inspect the NLG actuator attachment lever for cracks and damage in the areas shown in paragraph 2 of the Instructions in Diamond Aircraft Work Instruction WI–MSB 42–136 and WI–MSB 42NG–078, Revision 1, dated January 24, 2019 (issued as one document) attached to Diamond Aircraft Mandatory Service Bulletin MSB 42–136/1 and MSB 42NG–078, dated January 24, 2019 (issued as one document) at the following applicable compliance times in paragraph (h)(1)(i) or (ii) of this AD:

(i) *For airplanes with an NLG assembly that has accumulated less than 1,800 hours TIS as of the effective date of this AD:* Within 200 hours TIS after the NLG assembly accumulates 1,800 hours TIS or within 12 months after the NLG assembly accumulates 1,800 hours TIS, whichever occurs first, and thereafter at intervals not to exceed 200 hours TIS; or

(ii) *For airplanes with an NLG assembly that has accumulated 1,800 or more hours TIS as of the effective date of this AD:* Within 210 hours TIS after the effective date of this AD or within 12 months after the effective date of this AD, whichever occurs first, and thereafter at intervals not to exceed 200 hours TIS.

(2) After each inspection required by paragraph (h)(1) of this AD, if there is a crack or damage on the NLG actuator attachment lever, before further flight, replace the NLG leg assembly with an airworthy part as defined by this AD.

(3) As of the effective date of this AD, do not install an NLG leg assembly on any airplane unless it is an airworthy part as defined by this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, 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 local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD or email: *9-AVS-AIR-730-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Related Information

(1) For more information about this AD, contact Penelope Trease, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 26805 E 68th Avenue, Denver, CO 80249; phone: (303) 342–1094; email: *penelope.trease@faa.gov.*

(2) Refer to European Union Aviation Safety Agency (EASA) AD 2019–0066, dated March 27, 2019, for more information. You may examine the EASA AD in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0602.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference 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 the AD specifies otherwise.

(i) Diamond Aircraft Mandatory Service Bulletin MSB 42–136/1 and MSB 42NG–078, dated January 24, 2019 (issued as one document) published with Diamond Aircraft Work Instruction WI–MSB 42–136 and WI–MSB 42NG–078, Revision 1, dated January 24, 2019 (issued as one document) attached.

(ii) [Reserved]

(3) For service information identified in this AD, contact Diamond Aircraft Industries GmbH, N.A. Otto-Straße 5, A–2700 Wiener Neustadt, Austria; phone: +43 2622 26700; fax: +43 2622 26780; email: *office@diamond-air.at;* website: *https://www.diamondaircraft.com.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on October 13, 2021.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–25011 Filed 11–15–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31397; Amdt. No. 3981]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPS) and associated Takeoff Minimums and Obstacle Departure procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective November 16, 2021. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 16, 2021.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30. 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC, 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg 29 Room 104, Oklahoma City, OK 73169. Telephone (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, 8260–15B, when required by an entry on 8260–15A, and 8260–15C.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers or aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the typed of SIAPS, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flights safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Lists of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on October 29, 2021.

Thomas J. Nichols,

Flight Standards Service Manager, Aviation Safety, Standards Section, Flight Procedures & Airspace Group Flight Technologies & Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CRF part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 2 December 2021

Sand Point, AK, PASD, RNAV (GPS) Y RWY 14, Orig
Sand Point, AK, PASD, RNAV (GPS) Z RWY 14, Amdt 2
Chandler, AZ, KCHD, RNAV (GPS) RWY 4R, Amdt 1
Springerville, AZ, Springerville Muni, Takeoff and Minimums and Obstacle DP, Orig-A
El Monte, CA, KEMT, RNAV (GPS)-B, Orig-A
Lake Wales, FL, X07, RNAV (GPS) RWY 6, Amdt 1
Lake Wales, FL, X07, RNAV (GPS) RWY 24, Amdt 1
Lake Wales, FL, Lake Wales Muni, Takeoff Minimums and Obstacle DP, Amdt 1
St Simons Island, GA, KSSI, RNAV (GPS) RWY 4, Orig-C
St Simons Island, GA, KSSI, RNAV (GPS) RWY 22, Orig-B
Chicago, IL, KMDW, RNAV (GPS) Z RWY 13C, Amdt 2A
Chicago, IL, KORD, RNAV (GPS) RWY 9R, Amdt 5
Chicago, IL, KORD, RNAV (GPS) Z RWY 27L, Amdt 5
Chicago, IL, KORD, RNAV (RNP) Y RWY 27L, Amdt 2
Leoti, KS, 3K7, RNAV (GPS) RWY 17, Orig
Leoti, KS, 3K7, RNAV (GPS) RWY 35, Orig
Leoti, KS, Mark Hoard Meml, Takeoff Minimums and Obstacle DP, Orig
Joplin, MO, KJLN, ILS OR LOC/NDB RWY 13, Amdt 1
Bismarck, ND, KBIS, RADAR–1, Amdt 3C
Pembina, ND, KPMB, VOR–A, Orig-A, CANCELLED
Walhalla, ND, 96D, RNAV (GPS) RWY 33, Orig-B
Portsmouth, NH, KPSM, ILS OR LOC RWY 16, Amdt 3
Portsmouth, NH, KPSM, ILS OR LOC RWY 34, Amdt 4
Portsmouth, NH, KPSM, RNAV (GPS) RWY 16, Amdt 3
Portsmouth, NH, KPSM, RNAV (GPS) RWY 34, Amdt 2
Hamilton, NY, KVGC, RNAV (GPS) RWY 17, Amdt 1A
Rochester, NY, KROC, RNAV (GPS) RWY 7, Amdt 1B
Skaneateles, NY, 6B9, RNAV (GPS)-A, Orig
Skaneateles, NY, 6B9, RNAV (GPS)-B, Orig
Skaneateles, NY, 6B9, VOR OR GPS–A, Orig-B, CANCELLED
Carrollton, OH, Carroll County-Tolson, Takeoff Minimums and Obstacle DP, Amdt 5
San Antonio, TX, KSAT, ILS OR LOC RWY 31L, Amdt 11

[FR Doc. 2021–24850 Filed 11–15–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31398; Amdt. No. 3982]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective November 16, 2021. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 16, 2021.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, email *fr.inspection@nara.gov* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and

Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on October 29, 2021.

Thomas J. Nichols,

Flight Standards Service Manager, Aviation Safety, Standards Section, Flight Procedures & Airspace Group Flight Technologies & Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, CFR part 97, (is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
2–Dec–21	ME	Biddeford	Biddeford Muni	1/1082	10/4/21	This NOTAM, published in Docket No. 31396, Amdt No. 3980, TL 21–25, (86 FR 59848, October 29, 2021) is hereby rescinded in its entirety.
2–Dec–21	KY	Morehead	Morehead-Rowan County Clyde A Thomas Rgnl.	1/0010	10/7/21	RNAV (GPS) RWY 2 , Amdt 1.
2–Dec–21	KY	Morehead	Morehead-Rowan County Clyde A Thomas Rgnl.	1/0011	10/7/21	RNAV GPS RWY 20, Amdt 1.
2–Dec–21	GA	Mc Rae	Telfair-Wheeler	1/0837	10/7/21	RNAV (GPS) RWY 3, Orig-A.
2–Dec–21	GA	Mc Rae	Telfair-Wheeler	1/0869	10/7/21	RNAV (GPS) RWY 21, Amdt 1C.
2–Dec–21	FL	Leesburg	Leesburg Intl	1/0912	10/7/21	RNAV (GPS) RWY 31, Amdt 1A.
2–Dec–21	AK	Tanana	Ralph M Calhoun Meml	1/0913	10/19/21	RNAV (GPS) RWY 7, Orig-B.
2–Dec–21	AK	Tanana	Ralph M Calhoun Meml	1/0914	10/19/21	VOR/DME RWY 7, Amdt 2B.
2–Dec–21	AR	Little Rock	Bill And Hillary Clinton Ntl/Adams Fld	1/1024	10/8/21	RNAV (GPS) RWY 4L, Amdt 1E.
2–Dec–21	TX	Wichita Falls	Wichita Valley	1/1025	10/7/21	VOR–B, Amdt 6A.
2–Dec–21	IL	Danville	Vermilion Rgnl	1/1030	10/8/21	RNAV (GPS) RWY 3, Orig-A.
2–Dec–21	IL	Danville	Vermilion Rgnl	1/1032	10/8/21	ILS OR LOC RWY 21, Amdt 7A.
2–Dec–21	IL	Danville	Vermilion Rgnl	1/1033	10/8/21	RNAV (GPS) RWY 21, Orig-A.
2–Dec–21	IL	Danville	Vermilion Rgnl	1/1034	10/8/21	RNAV (GPS) RWY 34, Orig-A.
2–Dec–21	IL	Danville	Vermilion Rgnl	1/1035	10/8/21	VOR/DME RWY 3, Amdt 12A.
2–Dec–21	LA	Ruston	Ruston Rgnl	1/1044	10/8/21	RNAV (GPS) RWY 18, Orig-B.
2–Dec–21	LA	Ruston	Ruston Rgnl	1/1045	10/8/21	NDB RWY 18, Orig-E.
2–Dec–21	KS	Oakley	Oakley Muni	1/1175	10/19/21	NDB RWY 34, Amdt 3A.
2–Dec–21	NE	North Platte	North Platte Rgnl/Lee Bird Fld	1/1753	10/12/21	VOR RWY 35, Amdt 18C.
2–Dec–21	TN	Dayton	Mark Anton	1/2005	10/19/21	RNAV (GPS) RWY 21, Amdt 1A.
2–Dec–21	TN	Dayton	Mark Anton	1/2009	10/19/21	RNAV (GPS) RWY 3, Orig-A.
2–Dec–21	SC	Darlington	Darlington County	1/2134	10/19/21	RNAV (GPS) RWY 23, Orig-C.
2–Dec–21	SC	Darlington	Darlington County	1/2217	10/19/21	RNAV (GPS) RWY 5, Orig-D.
2–Dec–21	OH	Lima	Lima Allen County	1/2251	10/19/21	RNAV (GPS) RWY 28, Amdt 2B.
2–Dec–21	AK	Minchumina	Minchumina	1/3070	10/19/21	RNAV (GPS) RWY 3, Orig-C.
2–Dec–21	VA	Dublin	New River Valley	1/3123	10/19/21	VOR/DME RWY 6, Amdt 8.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
2–Dec–21	VA	Dublin	New River Valley	1/3124	10/19/21	RNAV (GPS) RWY 24, Amdt 1A.
2–Dec–21	VA	Dublin	New River Valley	1/3133	10/19/21	RNAV (GPS) RWY 6, Orig-A.
2–Dec–21	NE	Oshkosh	Garden County/King Rhiley Fld	1/3616	10/19/21	RNAV (GPS) RWY 12, Amdt 2B.
2–Dec–21	NE	Oshkosh	Garden County/King Rhiley Fld	1/3617	10/19/21	RNAV (GPS) RWY 30, Amdt 1A.
2–Dec–21	VA	Richmond	Richmond Exec-Chesterfield County	1/3623	10/19/21	RNAV (GPS) RWY 33, Orig-D.
2–Dec–21	VA	Richmond	Richmond Exec-Chesterfield County	1/3624	10/19/21	ILS OR LOC RWY 33, Amdt 2D.
2–Dec–21	MT	Livingston	Mission Fld	1/3627	10/19/21	RNAV (GPS) RWY 22, Orig-A.
2–Dec–21	MT	Livingston	Mission Fld	1/3628	10/19/21	VOR/DME–B, Amdt 2.
2–Dec–21	WV	Parkersburg	Mid-Ohio Valley Rgnl	1/3633	10/19/21	RNAV (GPS) RWY 3, Amdt 2C.
2–Dec–21	WV	Parkersburg	Mid-Ohio Valley Rgnl	1/3635	10/19/21	RNAV (GPS) RWY 10, Orig-C.
2–Dec–21	WV	Parkersburg	Mid-Ohio Valley Rgnl	1/3636	10/19/21	RNAV (GPS) RWY 21, Amdt 2D.
2–Dec–21	WV	Parkersburg	Mid-Ohio Valley Rgnl	1/3637	10/19/21	RNAV (GPS) RWY 28, Orig-C.
2–Dec–21	WV	Parkersburg	Mid-Ohio Valley Rgnl	1/3638	10/19/21	VOR RWY 21, Amdt 17D.
2–Dec–21	WV	Parkersburg	Mid-Ohio Valley Rgnl	1/3640	10/19/21	ILS OR LOC RWY 3, Amdt 14C.
2–Dec–21	AZ	Douglas Bisbee	Bisbee Douglas Intl	1/3831	10/19/21	RNAV (GPS) RWY 17, Orig-A.
2–Dec–21	AZ	Douglas Bisbee	Bisbee Douglas Intl	1/3832	10/19/21	VOR/DME RWY 17, Amdt 6A.
2–Dec–21	AZ	Douglas Bisbee	Bisbee Douglas Intl	1/3833	10/19/21	VOR RWY 17, Amdt 3A.
2–Dec–21	IN	Rochester	Fulton County	1/4141	10/19/21	RNAV (GPS) RWY 11, Amdt 1.
2–Dec–21	IN	Rochester	Fulton County	1/4148	10/19/21	RNAV (GPS) RWY 29, Amdt 1.
2–Dec–21	ME	Biddeford	Biddeford Muni	1/4605	10/18/21	RNAV (GPS) RWY 6, Orig-A.
2–Dec–21	KS	Belleville	Belleville Muni	1/4674	10/19/21	RNAV (GPS) RWY 18, Orig-C.
2–Dec–21	KS	Belleville	Belleville Muni	1/4676	10/19/21	RNAV (GPS) RWY 36, Orig-C.
2–Dec–21	KS	Belleville	Belleville Muni	1/4677	10/19/21	VOR–A, Amdt 3E.
2–Dec–21	TX	Fredericksburg	Gillespie County	1/5199	10/19/21	RNAV (GPS) RWY 14, Amdt 1C.
2–Dec–21	TX	Fredericksburg	Gillespie County	1/5201	10/19/21	RNAV (GPS) RWY 32, Amdt 1D.
2–Dec–21	KS	Oakley	Oakley Muni	1/5756	10/19/21	RNAV (GPS) RWY 34, Orig-A.
2–Dec–21	AK	Anchorage	Ted Stevens Anchorage Intl	1/6735	10/18/21	ILS OR LOC RWY 7R, ILS RWY 7R (SA CAT I), ILS RWY 7R (CAT II AND III), Amdt 4.
2–Dec–21	TX	Galveston	Scholes Intl At Galveston	1/7013	10/19/21	RNAV (GPS) RWY 18, Amdt 2B.
2–Dec–21	TX	Galveston	Scholes Intl At Galveston	1/7014	10/19/21	ILS OR LOC RWY 14, Amdt 12C.
2–Dec–21	TX	Galveston	Scholes Intl At Galveston	1/7015	10/19/21	RNAV (GPS) RWY 14, Amdt 1A.
2–Dec–21	TX	Galveston	Scholes Intl At Galveston	1/7016	10/19/21	RNAV (GPS) RWY 32, Amdt 1A.
2–Dec–21	TX	Galveston	Scholes Intl At Galveston	1/7024	10/19/21	RNAV (GPS) RWY 36, Amdt 1A.
2–Dec–21	TX	Galveston	Scholes Intl At Galveston	1/7025	10/19/21	VOR RWY 14, Amdt 4C.
2–Dec–21	TX	Levelland	Levelland Muni	1/7089	10/19/21	RNAV (GPS) RWY 17, Amet 1B.
2–Dec–21	TX	Levelland	Levelland Muni	1/7111	10/19/21	RNAV (GPS) RWY 35, Amdt 1B.
2–Dec–21	VA	Stafford	Stafford Rgnl	1/7599	10/19/21	ILS OR LOC RWY 33, Orig-A.
2–Dec–21	VA	Stafford	Stafford Rgnl	1/7602	10/19/21	VOR RWY 33, Amdt 1.
2–Dec–21	IL	Mount Sterling	Mount Sterling Muni	1/8504	10/19/21	VOR/DME–A, Amdt 1.
2–Dec–21	IL	Mount Sterling	Mount Sterling Muni	1/8508	10/19/21	RNAV (GPS) RWY 36, Orig-A.
2–Dec–21	IL	Mount Sterling	Mount Sterling Muni	1/8510	10/19/21	RNAV (GPS) RWY 18, Orig-A.
2–Dec–21	MN	St Cloud	St Cloud Rgnl	1/8711	10/19/21	VOR RWY 31, Orig-B.
2–Dec–21	MN	St Cloud	St Cloud Rgnl	1/8715	10/19/21	RNAV (GPS) RWY 23, Orig-B.
2–Dec–21	OH	Celina	Lakefield	1/8793	10/19/21	RNAV (GPS) RWY 8, Orig.
2–Dec–21	OH	Celina	Lakefield	1/8796	10/19/21	RNAV (GPS) RWY 26, Orig.
2–Dec–21	FL	Perry	Perry-Foley	1/8850	10/19/21	RNAV (GPS) RWY 18, Amdt 1A.
2–Dec–21	FL	Perry	Perry-Foley	1/8853	10/19/21	RNAV (GPS) RWY 36, Amdt 1A.
2–Dec–21	MN	Paynesville	Paynesville Muni	1/8858	10/19/21	RNAV (GPS) RWY 29, Amdt 1B.
2–Dec–21	MN	Paynesville	Paynesville Muni	1/8862	10/19/21	RNAV (GPS) RWY 11, Amdt 1B.
2–Dec–21	MN	St Cloud	St Cloud Rgnl	1/9013	10/19/21	RNAV (GPS) RWY 13, Amdt 1.
2–Dec–21	MN	St Cloud	St Cloud Rgnl	1/9016	10/19/21	RNAV (GPS) RWY 5, Orig-B.
2–Dec–21	MN	St Cloud	St Cloud Rgnl	1/9018	10/19/21	ILS OR LOC/DME RWY 13, Amdt 1.
2–Dec–21	MN	St Cloud	St Cloud Rgnl	1/9020	10/19/21	ILS OR LOC RWY 31, Amdt 3B.
2–Dec–21	MN	St Cloud	St Cloud Rgnl	1/9022	10/19/21	RNAV (GPS) RWY 31, Amdt 1A.
2–Dec–21	OH	Lima	Lima Allen County	1/9191	10/19/21	ILS OR LOC RWY 28, Amdt 5A.
2–Dec–21	FM	Kosrae	Kosrae	1/9377	10/13/21	NDB–A, Orig-C.
2–Dec–21	FM	Kosrae	Kosrae	1/9384	10/13/21	RNAV (GPS) RWY 23, Orig-B.
2–Dec–21	FM	Kosrae	Kosrae	1/9386	10/13/21	RNAV (GPS) RWY 5, Orig-B.
2–Dec–21	TX	Gladewater	Gladewater Muni	1/9756	10/7/21	RNAV (GPS) RWY 14, Orig-C.
2–Dec–21	TX	Gladewater	Gladewater Muni	1/9764	10/7/21	RNAV (GPS) RWY 32, Orig-B.

[FR Doc. 2021–24851 Filed 11–15–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Office of the Under-Secretary for Economic Affairs

15 CFR Part 1500

[Docket No.: 210820–0165]

RIN 0605–AA53

Concrete Masonry Products Research, Education, and Promotion Order: Delayed Effective Date

AGENCY: Under-Secretary for Economic Affairs, United States Department of Commerce.

ACTION: Final rule; delay of effective date.

SUMMARY: This document delays the effective date of the final rule published on September 15, 2021, setting forth the proposed Concrete Masonry Products Research, Education, and Promotion Order, as authorized by the Concrete Masonry Products Research, Education, and Promotion Act of 2018, which establishes a Concrete Masonry Products Board (Board) composed of industry members appointed by the Secretary of Commerce (Secretary) to develop and implement programs of research, education, and promotion in the concrete masonry products industry. The effective date is delayed from November 29, 2021, to December 18, 2021. There have been longer-than-expected delays in delivery of timely completed ballots, and the Department wants to ensure it has time to adequately review and process all ballots received. The change in the effective date of the Order does not affect the referendum period which ends on November 15. If the referendum fails, the Department will publish a document in the **Federal Register** to withdraw the final rule before the effective date.

DATES: Effective November 16, 2021, the effective date of the final rule published September 15, 2021, at 86 FR 51456, is delayed until December 18, 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Thompson, Communications for the Commerce Checkoff Implementation Program, Office of the Under Secretary for Economic Affairs, telephone: (202) 482–0671 or via electronic mail: *michael.thompson@trade.gov.*

SUPPLEMENTARY INFORMATION: The Department of Commerce published a final rule on September 15, 2021 (86 FR 51456), establishing a Concrete Masonry Products Research, Education, and Promotion Order, as authorized by the Concrete Masonry Products Research, Education, and Promotion Act of 2018. The effective date of the final rule was November 29, 2021. This document delays that date to December 18, 2021, to allow the Department adequate time to review and process all ballots received.

Dated: November 9, 2021.

Kenneth White,

Senior Policy Analyst, Under Secretary for Economic Affairs.

[FR Doc. 2021–24954 Filed 11–15–21; 8:45 am]

BILLING CODE 3510–20–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R10–OAR–2020–0305; FRL–8878–02–R10]

Air Plan Approval; ID; West Silver Valley Redesignation to Attainment for the 2012 Annual $PM_{2.5}$ Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is redesignating the West Silver Valley, Idaho nonattainment area to attainment for the 2012 annual fine particulate matter ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS). EPA is also approving a maintenance plan for the area that demonstrates continued attainment of the 2012 $PM_{2.5}$ NAAQS through the year 2031, which Idaho submitted along with the redesignation request for inclusion into the Idaho State Implementation Plan (SIP). Additionally, EPA is approving the 2031 motor vehicle emissions budgets included in Idaho's maintenance plan for $PM_{2.5}$, nitrogen oxides and volatile organic compounds. EPA is taking this action pursuant to the Clean Air Act (CAA or the Act).

DATES: This action is effective on December 16, 2021.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2020–0305. 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.,* CBI 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 through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Claudia Vaupel, (206) 553–6121, *vaupel.claudia@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, it is intended to refer to EPA.

I. Background

On June 2, 2020, Idaho submitted a request for EPA to redesignate the West Silver Valley area to attainment for the 2012 annual $PM_{2.5}$ NAAQS under section 107(d)(3)(E) of the CAA. On September 15, 2021, EPA proposed to approve Idaho's SIP revision (86 FR 51318). An explanation of the CAA requirements, a detailed analysis of the submittal, and the EPA's reasons for approval were provided in the notice of proposed rulemaking. The public comment period for this proposed rulemaking closed on October 15, 2021. EPA received no comments during the public comment period.

II. Final Action

EPA is redesignating the West Silver Valley 2012 annual $PM_{2.5}$ nonattainment area and is approving the associated maintenance plan and motor vehicle emission budgets for the area. The designation status of the West Silver Valley under 40 CFR part 81 will be revised to attainment upon the effective date of this final action.

III. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

• Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and it will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by JANUARY 18, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: November 4, 2021.

Michelle L. Pirzadeh,

Acting Regional Administrator, Region 10.

For the reasons set forth in the preamble, 40 CFR parts 52 and 81 are amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart N—Idaho

■ 2. In § 52.670, the table in paragraph (e) is amended by adding an entry at the end of the table for ''West Silver Valley $PM_{2.5}$ Nonattainment Area Redesignation Request and Maintenance Plan'' to read as follows:

§ 52.670 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED IDAHO NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Comments
*	*	*	*	*
West Silver Valley $PM_{2.5}$ Maintenance Plan.	West Silver Valley, ID	6/2/2020	11/16/2021, [INSERT **FEDERAL REGISTER** CITATION].	

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 3. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 4. In § 81.313 amend in the table entitled ''Idaho—2012 Annual $PM_{2.5}$ NAAQS'' by revising the entry for ''Shoshone County (part)'' to read as follows:

§ 81.313 Idaho.

* * * * *

IDAHO—2012 ANNUAL $PM_{2.5}$ NAAQS

[Primary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
West Silver Valley, ID:				

IDAHO—2012 ANNUAL $PM_{2.5}$ NAAQS—Continued

[Primary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Shoshone County (part) ..... That portion of Shoshone County, which is described as follows: T50N, R02E, Sections 14, 15, 22–27, 29–36; T49N, R01E, Sections 2, 11–14, 23–26, 35, 36 and Sections 10,15, 22, 27, 34 east of Kootenai County boundary; T49N, R02E, Sections 1–36; T49N, R03E, Sections 7, 13–36; T49N, R04E, Sections 19, 30, 31; T48N, R01E, Sections 1, 2, 11–14, 22–27, 34–36 and Sections 3, 10, 15 east of Kootenai County boundary; T48N, R02E, Sections 1–36; T48N, R03E, Sections 2–10, 16–20, 30, 31; T48N, R03E, Section 1, NWNW, SWNW, NWSW, SWSW; T48N, R03E, Section 11, NW¼, NE¼, NWSW, NESW, NWSE, NESE; T48N, R03E, Section 12, NWNW, SWNW, NWSW; T47N, R01E, Sections 1–3, 10–15, 22–27; T47N, R02E, Sections 1–23, 28–30; T47N, R03E, Sections 5–8, 17, and 18.	11/16/2021	Attainment.		
* * * * * * *				

[1] Includes areas of Indian country located in each county or area, except as otherwise specified.
[2] This date is April 15, 2015, unless otherwise noted.

* * * * *

[FR Doc. 2021–24966 Filed 11–15–21; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 86, No. 218
Tuesday, November 16, 2021

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 ENERGY

10 CFR Parts 429 and 431

[EERE–2019–BT–STD–0018]

RIN 1904–AE12

Energy Conservation Program: Energy Conservation Standards for Distribution Transformers, Webinar and Availability of the Preliminary Technical Support Document

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Reopening of public comment period.

SUMMARY: On August 27, 2021, the U.S. Department of Energy (''DOE'') published a notification of a webinar and availability of preliminary technical support document that DOE conducted for purposes of evaluating energy conservation standards for distribution transformers. The notification provided an opportunity for submitting written comments, data, and information by November 10, 2021. DOE received requests from Cleveland-Cliffs Steel Corporation (Cleveland-Cliffs) and the National Electrical Manufacturers Association (NEMA) asking DOE for a 30-day extension of the public comment period. DOE has reviewed this request and is reopening the public comment period to allow public comments to be submitted until December 10, 2021.

DATES: The comment period for the RFI published on August 27, 2021 (86 FR 48058) is reopened. DOE will accept comments, data, and information regarding this notification received no later than December 10, 2021.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2019–BT–STD–0018, by any of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.

2. *Email:* To *DistributionTransfromers 2019STD0018@ee.doe.gov.* Include docket number EERE–2019–BT–STD–0018 in the subject line of the message.

No telefacsimiles (''faxes'') will be accepted.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including the Federal eRulemaking Portal, email, postal mail, or hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing Covid–9 pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this change poses an undue hardship, please contact Appliance Standards Program staff at (202) 586–1445 to discuss the need for alternative arrangements. Once the Covid–19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, public meeting transcripts, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at *www.regulations.gov/docket?D=EERE-2019-BT-STD-0018.* The docket web page contains instructions on how to access all documents, including public comments in the docket.

FOR FURTHER INFORMATION CONTACT:

Mr. Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9870. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Matthew Ring, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–2555. Email: *matthew.ring@hq.doe.gov.*

For further information on how to submit a comment or review other public comments and the docket contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: On August 27, 2021, DOE published a notification announcing the availability of a technical support document and notification of a webinar on the preliminary analysis that DOE conducted for purposes of evaluating energy conservation standards for distribution transformers. 86 FR 48058. This webinar was held on September 29, 2021 and covered the analytical framework, models, and tools that DOE is using to evaluate potential standards for this equipment; the results of preliminary analyses performed by DOE for this equipment; the potential energy conservation standard levels derived from these analyses that DOE could consider for this product should it determine that proposed amendments are necessary; and any issues relevant to the evaluation of energy conservation standards for distribution transformers. In addition, the notification announced that DOE will be accepting written comments on these subjects on or before, November 10, 2021.

On October 29, 2021, NEMA requested a 30-day extension of the public comment period for this preliminary analysis. NEMA commented that given the volume of DOE analysis and number of questions posted, more time is needed to gather NEMA members together and prepare detailed industry responses. NEMA stated that manufacturers continue to face challenges in their businesses during the continued global pandemic and other supply chain disruptions and that more time will give greater opportunity to research and communicate accurate data and responses. (NEMA, No. 43 at p. 1) [1]

[1] The parenthetical reference provides a reference for information located in DOE's rulemaking docket. (Docket No. EERE-2019-BT-STD-0018, which is maintained at *www.regulations.gov/docket/EERE-2019-BT-STD-0018*). The references are arranged as follows: (Commenter name,

Cleveland-Cliffs also requested a 30-day extension of the public comment period for this preliminary analysis on November 5, 2021. Cleveland-Cliffs stated in their request that they are the only company in North America that procures Grain Oriented Electrical Steel, which is a critical and irreplaceable material used in distribution and dry-type transformers. Cleveland Cliff explained in their request that the preliminary analysis and technical support document is comprehensive and lengthy and that given the potentially significant impacts to transformer industry and specifically core steel selection, more time is needed to fully understand the impact to Cleveland-Cliffs' customer base and their business. (Cleveland-Cliffs, No. 44 at p. 1) [2]

DOE has reviewed the requests and is reopening the comment period to allow additional time for interested parties to submit comments. Therefore, DOE is reopening the comment period until December 10, 2021.

Signing Authority

This document of the Department of Energy was signed on November 9, 2021, by Kelly Speakes-Backman, Principal Deputy Assistant Secretary and Acting Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 10, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–24929 Filed 11–15–21; 8:45 am]

BILLING CODE 6450–01–P

comment docket ID number, page of that document).

[2] The parenthetical reference provides a reference for information located in DOE's rulemaking docket. (Docket No. EERE–2019–BT–STD–0018, which is maintained at *www.regulations.gov/docket/EERE-2019-BT-STD-0018*). The references are arranged as follows: (Commenter name, comment docket ID number, page of that document).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1004; Project Identifier MCAI–2021–00480–E]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG (Type Certificate Previously Held by Rolls-Royce plc) Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Rolls-Royce Deutschland Ltd & Co KG (RRD) RB211 Trent 875–17, 877–17, 884–17, 884B–17, 892–17, 892B–17, and 895–17 model turbofan engines. This proposed AD was prompted by findings during engine overhaul of corrosion on the low-pressure compressor (LPC) front case assembly. This proposed AD would require inspection of the LPC front case assembly and, depending on the result of the inspection, accomplishment of the applicable corrective action(s), as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by January 3, 2022.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For material that is proposed for IBR in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu.* For RRD service information identified in this NPRM, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; phone: +44 (0)1332 242424; fax: +44 (0)1332 249936; website: *https://www.rolls-royce.com/contact-us.aspx.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759. The EASA material is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1004.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1004; 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 NPRM, the EASA AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Nicholas Paine, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7116; email: *nicholas.j.paine@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–1004; Project Identifier MCAI–2021–00480–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM

contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Nicholas Paine, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0114, dated April 23, 2021 (EASA AD 2021–0114), to correct an unsafe condition for certain RRD RB211 Trent 875–17, 877–17, 884–17, 884B–17, 892–17, 892B–17, and 895–17 model turbofan engines.

This proposed AD was prompted by findings during engine overhaul of corrosion on the LPC front case assembly caused by excessive movement between the Kevlar wrap and the fan case, which resulted in the anti-corrosion paint fretting away. The FAA is proposing this AD to address corrosion on the LPC front case assembly. This condition, if not addressed, could affect the containment integrity of the LPC front case assembly during a fan blade release event, resulting in damage to the airplane, or reduced control of the airplane.

See EASA AD 2021–0114 for additional background information.

FAA's Determination

These engines have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified about the unsafe condition described in the EASA AD referenced in this AD. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2021–0114. EASA AD 2021–0114 specifies actions for inspecting the LPC front case assembly and, depending on the result of the inspection, corrective action. 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 **ADDRESSES**.

Other Related Service Information

The FAA reviewed Rolls-Royce RB211 Trent 800 Series Propulsion Systems Alert Non-Modification Service Bulletin RB.211–72–AG774, Revision 4, dated October 13, 2020 (the NMSB). The NMSB specifies procedures for inspecting the LPC front case assembly for corrosion and taking corrective action.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2021–0114, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD and except as discussed under ''Differences Between this Proposed AD and the EASA AD.''

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, the FAA proposes to incorporate EASA AD 2021–0114 in the FAA final rule. This proposed AD would require compliance with EASA AD 2021–0114 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2021–0114 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2021–0114. Service information specified by EASA AD 2021–0114 that is required for compliance with it will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1004 after the FAA final rule is published.

Differences Between This Proposed AD and the EASA AD

Qualified Shop Visit

EASA AD 2021–0114 defines a qualified shop visit as any scheduled shop visit where the affected part is exposed and substantial rebuild has not yet started, except shop visits for serviceability only. This proposed AD defines a qualified shop visit as the induction of an engine into the shop after the effective date of this AD for maintenance involving the separation of pairs of major mating engine flanges, with the exception of the separation of engine flanges solely for the purposes of transportation of the engine without subsequent engine maintenance.

Effective Date

Where EASA AD 2021–0114 requires compliance from its effective date, this proposed AD would require using the effective date of this AD.

Compliance

Where the service information referred to in EASA AD 2021–0114 specifies to inspect the affected part and contact the manufacturer for repair instructions if any corrosion is found exceeding the criteria as specified in the NMSB, this AD requires the removal of the affected LPC front case assembly from service if corrosion is found that exceeds the criteria specified in Appendix 2 of the NMSB.

Remarks

This AD does not mandate compliance with the ''Remarks'' section of EASA AD 2020–0114.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 98 engines installed on airplanes of U.S. Registry.

The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Perform ultrasonic inspection	8 work-hours × $85 per hour = $680	$0	$680	$66,640
Rework the LPC front case assembly	200 work-hours × $85 per hour = $17,000	18,724	35,724	3,500,952

The FAA estimates the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. The FAA has no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace the LPC front case assembly	140 work-hours × $85 per hour = $11,900	$932,000	$943,900

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

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would 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 this proposed regulation:

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

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

(3) Would 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 Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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:

Rolls-Royce Deutschland Ltd & Co KG (Type Certificate previously held by Rolls-Royce plc): Docket No. FAA–2021–1004; Project Identifier MCAI–2021–00480–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 3, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce Deutschland Ltd & Co KG (RRD) (Type Certificate previously held by Rolls-Royce plc) RB211 Trent 875–17, RB211 Trent 877–17, RB211 Trent 884–17, RB211 Trent 884B–17, RB211 Trent 892–17, RB211 Trent 892B–17, and RB211 Trent 895–17 model turbofan engines, as identified in EASA AD 2021–0114, dated April 23, 2021 (EASA AD 2021–0114).

(d) Subject

Joint Aircraft System Component (JASC) Code 7230, Turbine Engine Compressor Section.

(e) Unsafe Condition

This AD was prompted by findings during engine overhaul of corrosion on the low-pressure compressor (LPC) front case assembly caused by excessive movement between the Kevlar wrap and the fan case, which resulted in the anti-corrosion paint fretting away. The FAA is issuing this AD to address corrosion on the LPC front case assembly. The unsafe condition, if not addressed, could result in reduced integrity of the LPC front case assembly during a fan blade release, resulting in damage to the airplane or reduced control of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraph (h) of this AD: Perform all required actions within the compliance times specified in, and in accordance with, EASA AD 2021–0114.

(h) Exceptions to EASA AD 2021–0114

(1) Where EASA AD 2021–0114 requires compliance from its effective date, this proposed AD would require using the effective date of this AD.

(2) Where EASA AD 2021–0114 defines a qualified shop visit as any scheduled shop visit where the affected part is exposed and substantial rebuild has not yet started, this AD defines a qualified shop visit as the induction of an engine into the shop after the effective date of this AD for maintenance involving the separation of pairs of major mating engine flanges, with the exception of the separation of engine flanges solely for the purposes of transportation of the engine without subsequent engine maintenance, which does not constitute an engine shop visit.

(3) Where the service information referred to in EASA AD 2021–0114 specifies to contact the manufacturer for repair instructions if any corrosion is found exceeding the criteria as specified in the NMSB, this AD requires the removal of the affected LPC front case assembly from service if corrosion is found that exceeds the criteria specified in Appendix 2 of the NMSB.

(4) This AD does not mandate compliance with the ''Remarks'' section of EASA AD 2021–0114.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2021–0114 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO 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 local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ECO Branch, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *ANE-AD-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Related Information

(1) For more information about EASA AD 2021–0114, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1004.

(2) For more information about this AD, contact Nicholas Paine, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7116; email: *nicholas.j.paine@faa.gov.*

(3) For RRD service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; phone: +44 (0)1332 242424; fax: +44 (0)1332 249936; website: *https://www.rolls-royce.com/contact-us.aspx.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

Issued on November 9, 2021.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24931 Filed 11–15–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1002; Project Identifier AD–2021–00332–R]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Sikorsky Aircraft Corporation Model S–76D helicopters. This proposed AD was prompted by reports that certain Thales global positioning system (GPS) satellite based augmentation system (SBAS) receivers provided, under certain conditions, erroneous outputs on aircraft positions. This proposed AD would require replacing affected GPS receivers and prohibit installing those GPS receivers. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by [January 3, 2022.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact your local Sikorsky Field Representative or Sikorsky's Service Engineering Group at Sikorsky Aircraft Corporation, Mailstop K100, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–946–4337 (1–800–Winged–S); email *wcs_cust_service_eng.gr-sik@lmco.com.* Operators may also log on to the Sikorsky 360 website at *https://www.sikorsky360.com.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1002; 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 NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Nicholas Rediess, Aviation Safety Engineer, Boston ACO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7159; fax: (781) 238–7199; email: *nicholas.rediess@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–1002; Project Identifier AD–2021–00332–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI

as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Nicholas Rediess, Aviation Safety Engineer, Boston ACO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7159; fax: (781) 238–7199; email: *nicholas.rediess@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0004, dated January 11, 2019, and corrected on January 17, 2019 (EASA AD 2019–0004), to correct an unsafe condition for Thales AVS France SAS (Thales), formerly Thales Avionics SAS, GPS/SBAS receivers, Topstar 200 LPV, part number (P/N) C17149HA01 and C17149JA02, using SBAS, which are known to be installed on, but not limited to, certain Model ATR 42–500 and ATR 72–212A aeroplanes and Sikorsky Model S–76D helicopters. EASA advises of reports indicating that Thales GPS SBAS receivers provided, under certain conditions, erroneous outputs on aircraft positions. EASA AD 2019–0004 requires actions to prevent compromise of the safety margins when the receiver is used for Localizer Performance with Vertical guidance (LPV) and/or RNP–AR (Required Navigation Performance—Authorization Required) operations. Following the issuance of EASA AD 2019–0004, the FAA issued AD 2020–08–02, Amendment 39–21108 (85 FR 20586, April 14, 2020), to address the unsafe condition on these products.

After the issuance of EASA AD 2019–0004, EASA issued related EASA AD 2021–0013, dated January 13, 2021 (EASA AD 2021–0013), in response to a software update that was developed to ensure correct navigational performance of certain Thales GPS SBAS receivers installed on ATR–GIE Avions de Transport Régional, formerly EADS ATR—Alenia, Aerospatiale Matra ATR—ALENIA, Aerospatiale—Alenia, Aerospatiale—Aeritalia, Model ATR 42–500 and ATR 72–212A aeroplanes.

This proposed AD would require replacing affected GPS TopStar 200 LPV receivers installed on Sikorsky Aircraft Corporation Model S–76D helicopters. The FAA is proposing this AD to address erroneous aircraft position outputs from the GPS SBAS receivers, which could result in controlled flight into terrain, and subsequent loss of control of the helicopter.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Sikorsky S–76D Helicopter Service Bulletin SB 76–017, Basic Issue, dated May 11, 2021 (SB 76–017). SB 76–017 specifies procedures for removing, updating, and installing GPS TopStar 200 LPV receivers. SB 76–017 also provides instructions for sending the GPS receiver(s) to Thales Authorized Repair Stations for the software update.

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.

Proposed AD Requirements in This NPRM

This proposed AD would require replacing each affected GPS receiver and prohibit installing an affected GPS receiver on any helicopter.

Differences Between This Proposed AD and the Service Information

SB 76–017 requires returning the GPS receiver(s) to Thales Authorized Repair Stations for the software update, while this proposed AD would require replacing the GPS receiver(s) instead.

Costs of Compliance

The FAA estimates that this proposed AD would affect 22 helicopters of U.S. Registry and that operators may incur the following costs in order to comply with this proposed AD. Labor costs are estimated at $85 per work-hour.

Replacing a GPS receiver would take about 3 work-hours and parts would cost about $7,400, for an estimated cost of $7,655 per GPS receiver and $336,820 for the U.S. fleet.

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

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would 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 this proposed regulation:

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

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

(3) Would 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 Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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:

Sikorsky Aircraft Corporation: Docket No. FAA–2021–1002; Project Identifier AD–2021–00332–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 3, 2022.

(b) Affected ADs

This AD affects AD 2020–08–02, Amendment 39–21108 (85 FR 20586, April 14, 2020) (AD 2020–08–02).

(c) Applicability

This AD applies to Sikorsky Aircraft Corporation Model S–76D helicopters, certificated in any category, with Thales Global Positioning System (GPS) TopStar 200 LPV receiver part number (P/N) C17149HA01 installed.

(d) Subject

Joint Aircraft System Component (JASC) Code: 3457, Global Positioning System.

(e) Unsafe Condition

This AD was prompted by reports that certain Thales GPS satellite based augmentation system (SBAS) receivers provided, under certain conditions, erroneous outputs on aircraft positions. The unsafe condition, if not addressed, could result in controlled flight into terrain and loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Within 130 hours time-in-service after the effective date of this AD, replace each affected GPS receiver identified in paragraph (c) of this AD with GPS receiver P/N C17149RA01 in accordance with the Accomplishment Instructions, paragraphs A., C., and D., of Sikorsky S–76D Helicopter Service Bulletin SB 76–017, Basic Issue, dated May 11, 2021.

(2) As of the effective date of this AD, do not install a GPS receiver identified in paragraph (c) of this AD on any helicopter.

(3) Accomplishing paragraph (g)(1) of this AD terminates the requirements of AD 2020–08–02.

((h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston ACO Branch, Compliance & Airworthiness Division, 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 local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (i)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(i) Related Information

(1) For more information about this AD, contact Nicholas Rediess, Aviation Safety Engineer, Boston ACO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7159; fax: (781) 238–7199; email: *nicholas.rediess@faa.gov.*

(2) For service information identified in this AD, contact your local Sikorsky Field Representative or Sikorsky's Service Engineering Group at Sikorsky Aircraft Corporation, Mailstop K100, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–946–4337 (1–800–Winged–S); email *wcs_cust_service_eng.gr-sik@lmco.com.* Operators may also log on to the Sikorsky 360 website at *https://www.sikorsky360.com.* You may view this referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Issued on November 8, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24956 Filed 11–15–21; 8:45 am]

BILLING CODE 4910–13–P

NATIONAL TRANSPORTATION SAFETY BOARD

49 CFR Part 831

[Docket No.: NTSB–2021–0008]

RIN 3147–AA19

Commercial Space Investigations

AGENCY: National Transportation Safety Board (NTSB).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: For transparency of the agency's commercial space safety investigative authority, the NTSB is proposing adding Subpart F for Commercial Space Investigations to supplement its Investigation Procedures. By codifying its investigative role in commercial space transportation, the NTSB anticipates that Subpart F will enhance transportation safety by enabling the agency to carry out its statutory mission of conducting safety investigations, identifying necessary corrective actions, and preventing future space transportation accidents and incidents.

DATES: Submit written comments regarding this NPRM by January 18, 2022.

ADDRESSES: You may send comments, identified by Docket Number (No.) NTSB–2021–0008, by any of the following methods:

- *Federal e-Rulemaking Portal: https://www.regulations.gov.*
- *Email: rulemaking@ntsb.gov.*
- *Fax:* 202–314–6090.
- *Mail/Hand Delivery/Courier:* NTSB, Office of General Counsel, 490 L'Enfant Plaza East SW, Washington, DC 20594.

Instructions: All submissions in response to this NPRM must include Docket No. NTSB–2021–0008. All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket, go to *https://www.regulations.gov* and search Docket No. NTSB–2021–0008.

FOR FURTHER INFORMATION CONTACT: Kathleen Silbaugh, General Counsel, (202) 314–6080, *rulemaking@ntsb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

The NTSB is an independent investigatory agency charged with determining the facts, circumstances, and causes of transportation accidents and incidents. The NTSB's investigation procedures are contained in part 831, which is divided into subparts. The procedures applicable to all modes of transportation are contained in Subpart A of 49 CFR part 831. Subparts B–E are specific to the type of transportation; Subpart B, for example, focuses on Aviation Investigations. The agency notes that the commercial space industry is a unique mode of transportation and the investigatory needs of a commercial space accident and incident—such as the reporting of commercial space accidents and incidents, and the preservation of wreckage, evidence, and records—are distinct enough to warrant its own subpart. Thus, the NTSB proposes the addition of Subpart F for Commercial Space Investigations.

The agency's statutory authority to investigate commercial space launch accidents derives from 49 U.S.C. 1131(a)(1)(F), which provides in pertinent part that the NTSB shall investigate and establish the facts, circumstances, and probable cause of any other accident related to the transportation of any other individuals or property when the Board decides the accident is catastrophic, the accident involves problems of a recurring character, or investigating the accident would carry out the NTSB's statutory mandate.

The NTSB has exercised this authority and both led and supported commercial space launch and reentry investigations for more than 20 years. For example, the NTSB investigated the February 9, 1993, procedural anomaly associated with the launch of an Orbital Sciences Corporation Pegasus expendable launch vehicle. The NTSB investigated the incident and issued safety recommendations to the U.S. Department of Transportation (DOT), the National Aeronautics and Space Administration (NASA), and Orbital Sciences Corporation.

The NTSB also led the investigation of the SpaceShipTwo test flight breakup on October 31, 2014, involving one fatality and one serious injury. In testimony before the Subcommittee on Aviation, Committee on Transportation and Infrastructure, United States House of Representatives on February 27, 2018, the NTSB's then Director of Aviation Safety (Director) referenced the SpaceShipTwo investigation, stating: ''[f]oremost among the safety issues identified was the need to consider and protect against human error for safe manned spaceflight, which is the responsibility of designers, operators, and overseers.'' The Director further testified that there are circumstances within commercial space when the definition of accident or incident would not be met, and the NTSB would not be involved.

The NTSB was requested to assist several significant noncommercial space investigations; including those involving the Space Shuttle Columbia and NASA Genesis. On February 1, 2003, when the Space Shuttle Columbia fatally broke up while reentering Earth, NTSB investigators launched immediately to assist NASA and the Columbia Accident Investigation Board with the investigation. Several NTSB performance engineers, radar specialists and weather experts conducted ballistic analysis of the vehicle debris and examined radar and weather data to define the wreckage area in order to locate debris. Six NTSB investigators also helped NASA engineers reassemble the shuttle at Cape Canaveral. Overall, more than 50 NTSB employees supported this investigation.

For the September 8, 2004, NASA Genesis sample-return capsule crash in Tooele, Utah, an NTSB investigator launched to the accident scene with NASA's mishap investigation board to document the site and recover wreckage, and to set up the investigation and develop the investigation plan. The NTSB Systems and Materials Laboratory investigators also participated by examining and documenting the vehicle's wiring harness, and by developing and reviewing portions of the final report.

As in all transportation modes, the NTSB neither regulates commercial space nor finds fault when investigating mishaps; instead, the NTSB's investigations focus on safety issues. Accordingly, the NTSB is proposing Subpart F to clarify the extent of the agency's involvement and the process that will be followed by all parties in an NTSB-led commercial space investigation.

In conducting commercial space investigations, the NTSB adheres to the terms memorialized in a Memorandum of Agreement (Agreement) with the Federal Aviation Administration (FAA) [1] and in a Memorandum of Understanding (MOU) with the FAA and the United States Air Force (USAF).[2] It is important to note that the Agreement and MOU were developed before commercial human spaceflight, or reusable launch vehicles, was realistically foreseen and so only address cargo operations. The purpose of the Agreement and MOU was to specify when the NTSB would initiate an investigation into a commercial space mishap.

The 1975 Reimbursable Memorandum of Agreement between NTSB and DOT establishes the relationships, notification procedures, coordination requirements, and reporting responsibilities of both agencies. The Agreement further identifies and describes the conditions and agreements that exist regarding the exchange of data, availability of resources, conduct of studies and other services, and reimbursement for services rendered. Significantly, the Agreement acknowledges that while the objectives of both agencies' investigations are similar, the Agreement expounds on the differences—the NTSB investigates accidents to determine their probable cause and propose recommendations; whereas the DOT investigates to determine compliance with its regulations, evaluate improvements that should be made to existing standards and regulations and/or the transportation system to improve safety, and take appropriate enforcement action for any regulatory violation.

The Agreement categorizes each mode of transportation into separate appendices that detail the investigative procedures for a specific area of transportation. Appendix H addresses commercial travel, which was added in 1985 and subsequently revised in 1999 with non-substantive edits. Appendix H clarifies that the NTSB will investigate all commercial space launch accidents resulting in known impact of a commercial launch vehicle, its payload or any component thereof outside the impact limit lines designated by the launch range facility; or a fatality or serious injury as defined in 49 CFR 830.2 to any person who is not associated with commercial space launch activities and not located on the launch range facility; or any damage estimated to exceed $25,000 to property which is not associated with commercial space launch activities and which is not located on the launch range facility. Appendix H notes that the agreement does not impair the NTSB's authority to investigate other commercial space launch accidents which, in the judgment of the NTSB, are subject to section 304(a)(1)(F) of the Independent Safety Board Act of 1974.[3] Appendix H provides that any other investigations of commercial space launch accidents by the NTSB, other than those described, will be subject to the mutual agreement of the NTSB and the FAA's Associate Administrator for Commercial Space Transportation (AST).

The MOU became effective in September 2004 and establishes the relationship among the NTSB, FAA, and USAF during space launch accidents and provides a guide to the exchange of information and participation in accident investigations.[4]

Both the Agreement and the MOU remain in effect. Notably, at the time both documents were signed, commercial human space launches were not viable. With commercial human space flight now a reality, however, the NTSB believes codifying its authority to investigate commercial space safety accidents and incidents in Subpart F is necessary. By transitioning and updating the information from the Agreement and MOU to Subpart F, the commercial space industry would have better clarity on when the NTSB would initiate an investigation of a commercial space mishap. This process will also allow industry to provide feedback to the NTSB through the rulemaking process for any future updates as the industry develops.

The NTSB acknowledges that the DOT's authority to license commercial space transportation activities stems from 51 U.S.C. Chapter 509 for Commercial Space Launch Activities. Significantly, that authority did not include the process for investigating commercial space accidents and incidents independent of any NTSB intervention. While 51 U.S.C. 50917(a) does mention that in carrying out Chapter 509 the DOT Secretary may ''conduct investigations and inquiries,'' it does not appear that Chapter 509 was designed to give the DOT the

[1] *https://www.faa.gov/documentLibrary/media/Order/FAA_Order_8020.11D.pdf.*

[2] *https://www.faa.gov/space/legislation_regulation_guidance/media/mou_space_launch_accidents.pdf.*

[3] *https://www.ntsb.gov/safety/safety-studies/Documents/SIR9302.pdf.*

[4] *https://www.faa.gov/space/legislation_regulation_guidance/media/mou_space_launch_accidents.pdf.*

independent authority to investigate commercial space accidents and incidents. Introduced in the House of Representatives as the Commercial Space Launch Act (Act) on June 5, 1984, Congressman Harold Lee Volkmer clarified that the Act assigned the DOT the responsibility for issuing and enforcing commercial launch licenses, and for encouraging private sector use of government-developed space technology.[5] He noted that the purpose of the bill was to promote economic growth, simplify licensing, and have the DOT oversee commercial launch operations and issue licenses to conduct such activities.[6] Based on the deliberations of other representatives, it is evident that the intent of the legislation was to encourage private sector participation in the commercial space industry for the benefit of the U.S. economy. This intent was further expressed by Senator Paul Seward Trible, Jr., who explicitly stated that the central purpose of the legislation was to encourage the growth of a commercial space launch capability.[7] He continued that the bill designated the DOT as the lead agency to encourage and facilitate expendable launch vehicle commercialization.

The NTSB further acknowledges that the Congress does not wish to discourage development of this emerging industry and has charged the FAA to primarily focus on protection of the public and that the spaceflight participants are taking part in an inherently risky mode of transportation. The NTSB recognizes the ''learning period'' is still in effect that limits regulations ''restricting or prohibiting design features or operating practices,'' and that there is a need to restrict the release of certain sensitive information to safeguard critical defense-related technologies in order to protect United States national security and foreign policy objectives (International Traffic in Arms Regulations (ITAR), and Export Administration Regulation (EAR)).

Consistent with this legislative history and the NTSB's statutory authority, the Board believes that codifying NTSB's commercial space safety investigations in Subpart F is warranted under 49 U.S.C. 1131(a)(1)(F). The Board notes that per 49 U.S.C. 1131(b), the NTSB has statutory priority over any investigation by a U.S. department or agency. The issuance of Subpart F would resolve the matters currently addressed in Appendix H with the FAA.

II. Section-by-Section Analysis

831.70 Authority

Section 831.70 references the NTSB's statutory authority under 49 U.S.C. 1131(a)(1)(F), which provides that the NTSB shall investigate and establish the facts, circumstances, and probable cause of any other accident related to the transportation of any other individuals or property when the Board decides that the accident is catastrophic; the accident involves problems of a recurring character; or the investigation of the accident would carry out the NTSB's statutory authority.

831.71 Purpose

Section 831.71 specifies that Subpart F establishes the agency's safety investigative procedures for commercial space accidents or incidents.

831.72 Applicability

Section 831.72 clarifies that the NTSB would investigate a commercial space launch or reentry accident, but may investigate a commercial space launch or reentry incident licensed by FAA AST.

831.73 Definitions

Section 831.73 establishes the terminology used in Subpart F.

831.74 Immediate Notification

In the event of a commercial space launch or reentry accident or incident, § 831.74 requires that licensees and permittees immediately call the NTSB's Response Operation Center.

831.75 Information To Be Given in Notification

Section 831.75 establishes what must be reported in the event of a commercial space launch or reentry accident or incident.

831.76 Preservation of Commercial Space Launch or Reentry Vehicle Wreckage, Payload, and Records

Section 831.76 addresses what a licensee or permittee must do when preserving the wreckage, payload, and records. The preservation of materials, documents, data, and wreckage is essential for the NTSB's safety investigation and the accompanying safety recommendations.

831.77 Nature of Investigation

Section 831.77 clarifies why the NTSB conducts its safety investigations, and that the agency determines probable cause and issues safety recommendations. This section further clarifies that the agency does not investigate all incidents; whether the NTSB investigates a launch or reentry incident is contingent on the circumstances of the mishap.

831.78 Relationships With Other Agencies

Section 831.78 allows for participation of other Federal agencies, but establishes the limitations and expectations of the participants.

831.79 Request To Withhold Information

While § 831.13 is applicable to Subpart F, the NTSB is adding § 831.79 to address the protection of defense-related technologies. The regulation is intended to safeguard U.S. national security and further U.S. foreign policy objectives.

831.80 Provision and Dissemination of Investigative Information

Section 831.80 provides that § 831.13 applies to commercial space investigations, but adds that the release of information will comply with the applicable export control regulations.

831.81 Commercial Space Investigation Interviews

Section 831.81 supplements the provisions contained in § 831.7, but puts the public on notice that interviews or statements conducted during an NTSB commercial space investigation will become part of the public record subject to the applicable export control regulations.

III. Regulatory Analysis

Because the NTSB is an independent agency, this proposed rule does not require an assessment of its potential costs and benefits under section 6(a)(3) of Executive Order (E.O.) 12866, Regulatory Planning and Review, 58 FR 51735 (Sept. 30, 1993). In addition, the NTSB has considered whether this rule would have a significant economic impact on a substantial number of small entities, under the Regulatory Flexibility Act (5 U.S.C. 601–612). The NTSB 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.

The NTSB does not anticipate this rule will have a substantial, direct effect on state or local governments or will preempt state law; as such, this rule does not have implications for federalism under E.O. 13132, Federalism, 64 FR 43255 (Aug. 4, 1999).

This rule complies with all applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, 61 FR

[5] 98 Cong. Rec. H. 3942 (daily ed. June 5, 1984) (statement of Rep. Volkmer).

[6] *Id.*

[7] 98 Cong. Rec. H. 3942 (daily ed. Oct. 9, 1984) (statement of Sen. Trible).

4729 (Feb. 5, 1996), to minimize litigation, eliminate ambiguity, and reduce burden. The NTSB has evaluated this rule under: E.O. 12898, Federal Actions to Address Environmental Judice in Minority Populations and Low-Income Populations, 59 FR 7629 (Feb. 16, 1994); E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks, 62 FR 19885 (Apr. 21, 1997); E.O. 13175, Consultation and Coordination with Indian Tribal Governments, 65 FR 67249 (Nov. 6, 2000); E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use, 66 FR 28355 (May 18, 2001); and the National Environmental Policy Act, 42 U.S.C. 4321–47 The NTSB has concluded that this proposed rule neither violates nor requires further consideration under those orders, statutes, E.O.s, and acts.

The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3507(d)) requires that the NTSB consider the impact of paperwork and other information collection burdens imposed on the public. Here, proposed rule 831.74 directs the public to call the agency's Response Operations Center when reporting a commercial space accident or incident, and provide the information enumerated in proposed 49 CFR 831.75. The NTSB will use the information collected to determine whether to commence an investigation into the commercial space accident or incident. Additionally, the accuracy of the information collected will be used in issuing safety recommendations to prevent future commercial space accidents and incidents. However, because the NTSB anticipates that it will receive less than one notification of a mishap accident/incident per year, the agency will not submit an information collection request to the Office of Management and Budget. In other words, the NTSB is not imposing an information collection on ten or more persons to trigger the PRA.

List of Subjects in 49 CFR Part 831

Accident, Commercial space launch, Commercial space reentry, Incident, Mishap, Space transportation.

For the reasons set forth in the preamble, the NTSB proposes to add 49 CFR part 831 to read as follows:

PART 831—INVESTIGATION PROCEDURES

■ 1. The general authority citation for part 831 continues to read as follows:

Authority: 49 U.S.C. 1113(f).

■ 2. Add subpart F to read as follows:

Subpart F—Commercial Space Investigations

Sec.

Authority: 49 U.S.C. 1113(f), 1116, 1131(a)(1)(F); 49 CFR 831.2(d).

§ 831.70 Authority.

The NTSB conducts commercial space investigations under 49 U.S.C. 1131(a)(1)(F) and works closely with parties to the investigation to collect evidence related to a commercial launch or reentry accident. An investigation conducted under the authority of the NTSB has priority over any investigation conducted by another Federal agency, except those conducted by a commission initiated by the President of the United States.

§ 831.71 Purpose.

This subpart establishes investigative procedures specifically related to commercial space accidents or incidents.

§ 831.72 Applicability.

The regulations in this subpart apply when the NTSB is leading an investigation into a launch or reentry commercial space accident, or has elected to investigate a launch or reentry incident. This subpart pertains to:

(a) Initial notification and later reporting of commercial space launch and reentry accidents licensed by Federal Aviation Administration's (FAA) Associate Administrator for Commercial Space Transportation (AST), as specified in this part, wherever they occur.

(b) Preservation of launch or reentry vehicles, as specified in this part.

§ 831.73 Definitions.

As used in this subpart the following words or phrases are defined as follows:

Commercial space launch means a launch authorized to be conducted under a license or permit issued by the FAA.

Commercial space reentry means a reentry authorized to be conducted under a license or permit issued by the FAA.

Fatal injury means any injury which results in death within 30 days of the accident.

Launch or reentry accident means any mishap associated with an FAA-licensed or permitted activity resulting in:

(1) A fatal injury or serious injury to any person as a result of the operation of the vehicle; or

(2) The impact of hazardous debris outside the designated hazard area or designated landing site (excluding unmanned vehicles that cause no hazard to the public).

Launch or reentry incident means any mishap associated with an FAA-licensed or permitted activity resulting in:

(1) A malfunction of a safety-critical system (*i.e.,* flight termination system, etc.);

(2) A failure of the licensee's or permittee's safety organization, safety operations, or safety procedures; or

(3) A hazardous condition with increased likelihood of causing serious or fatal injuries to any person (*i.e.,* use of launch escape system).

Mishap means a launch or reentry accident, launch or reentry incident, failure to complete a launch or reentry as planned, or an unplanned event or series of events resulting in a fatality or serious injury.

Serious injury means an injury as defined under 49 CFR 830.2.

§ 831.74 Immediate notification.

In the event of a mishap, the licensee or permittee of any launch or reentry vehicle shall immediately notify the NTSB's Response Operations Center at 844–373–9922 or 202–314–6290.

§ 831.75 Information to be given in notification.

The notification required in § 831.74 shall contain the following information, if available:

(a) Date and time of the accident or incident;

(b) Launch vehicle;

(c) Launch/reentry licensee or permittee;

(d) Type of activity (launch, reentry, landing);

(e) Vehicle damage;

(f) Location of the launch or reentry vehicle with reference to some easily-defined geographical point;

(g) Number of persons involved, number killed, and number seriously injured; and

(h) Circumstances of the accident or incident.

§ 831.76 Preservation of commercial space launch or reentry vehicle wreckage, payload, and records.

(a) The licensee or permittee of a commercial space launch or reentry vehicle involved in an accident or incident for which notification must be given, is responsible for preserving the following until the Board takes custody thereof or a release is granted pursuant to § 831.12(b):

(1) Any wreckage and payload aboard the vehicle; and

(2) All records, including but not limited to all recording mediums, maintenance, and voice and video recorders, pertaining to the operation and maintenance of the launch or reentry vehicle.

(b) Prior to the time the Board or its authorized representative takes custody of the wreckage or payload, such wreckage or payload may not be disturbed or moved except to the extent necessary:

(1) To remove persons injured or trapped;

(2) To protect the wreckage from further damage; or

(3) To protect the public from injury.

(c) Where it is necessary to move the wreckage or payload, sketches, descriptive notes, and photographs shall be made, if possible, of the original positions and condition of the wreckage and any significant impact marks.

(d) The licensee or permittee of a launch or reentry vehicle involved in an accident or incident shall preserve and retain all streamed and digital data that is on board the launch or reentry vehicle, telemetered to an offsite location, or that is recorded remotely (*i.e.,* ground station, chase plane, etc.).

(e) The licensee or permittee of a launch or reentry vehicle involved in an accident or incident shall retain all records, reports, internal documents, and memoranda dealing with the accident or incident, until the Board authorizes its release.

§ 831.77 Nature of investigation.

The NTSB conducts investigations to determine the facts, conditions, and circumstances relating to a launch or reentry accident or incident. The NTSB uses these results to determine one or more probable causes, and to issue safety recommendations to prevent or mitigate the effects of a similar commercial space casualty launch or reentry accident or incident.

§ 831.78 Relationships with other agencies.

(a) The NTSB will provide for appropriate participation by other Federal agencies in any NTSB investigation. Such agencies may not participate in the NTSB's probable cause determination.

(b) Nothing in this section impairs the authority of any other Federal agency to investigate a commercial launch or reentry accident under applicable provisions of law. These agencies are expected to coordinate with the NTSB Investigator-in-Charge (IIC) to avoid interference with and duplication of the NTSB's investigative efforts.

§ 831.79 Request to withhold information.

In addition to the provisions established in § 831.6, the NTSB will not disclose any information subject to export control regulations related to defense and military technologies. The NTSB will coordinate with the appropriate government agencies to ensure all publicly-released investigative reports or public meetings comply with applicable regulations.

§ 831.80 Provision and dissemination of investigative information.

In addition to the provisions provided in § 831.13, the release of information will comply with the applicable export control regulations.

§ 831.81 Commercial space investigation interviews.

In addition to the provisions set forth in § 831.7, interviews or statements conducted during an NTSB commercial space investigation will become part of the public record subject to the applicable export control regulations.

Jennifer Homendy,

Chair.

[FR Doc. 2021–24766 Filed 11–15–21; 8:45 am]

BILLING CODE 7533–01–P

Notices

Federal Register
Vol. 86, No. 218
Tuesday, November 16, 2021

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.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2021–0072]

Notice of Request for Extension of Approval of an Information Collection; Agriculture Organisms and Vectors; Import and Transport Permits

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with the regulations for safe importation and transport of organisms and vectors.

DATES: We will consider all comments that we receive on or before January 18, 2022.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2021–0072 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2021–0072, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *www.regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information regarding the VS permitting process for organisms and vectors, contact Dr. Troy T. Bigelow, Senior Staff Veterinarian, Organisms and Vectors Permitting, Animal Products Import and Export, Strategy and Policy, VS, APHIS, 1920 Dayton Avenue, Ames, IA 50010, (301) 851–3464. For more information on the information collection reporting process, contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2483; *joseph.moxey@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Agriculture Organisms and Vectors; Import and Transport Permits.

OMB Control Number: 0579–0213.

Type of Request: Extension of approval of an information collection.

Abstract: The Animal Health Protection Act (AHPA) of 2002 (7 U.S.C. 8301 *et seq.*) authorizes the U.S. Department of Agriculture (USDA) to oversee the importation, entry, and movement in the United States of animals, pests or diseases, or any material or tangible object that could harbor them. Under the AHPA, USDA regulates certain organisms, vectors, and animal products that could pose a severe threat to animal health or to animal products through the risk of disease or pest introduction.

The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the AHPA within USDA. APHIS regulations for these activities are contained in 9 CFR part 94 (animals and animal products), 9 CFR part 95 (animal byproducts), and 9 CFR part 122 (organisms and vectors). There is also a requirement for an individual or entity, unless specifically exempted under the regulations, to apply for and be granted, by APHIS, a permit authorizing specific import or transport activities for regulated materials prior to receipt of the requested materials.

The permit application process entails the use of forms designed to obtain critical information concerning individuals or entities seeking a permit, as well as the specific characteristics of the material to be permitted. This data is needed, in part, to allow APHIS to assess the risk of importing or transporting the material, as well as the biosecurity and biosafety mitigations in place at the receiving location. This, in turn, enables APHIS to ensure that appropriate safeguard, containment, and disposal requirements commensurate with the risk of the materials are implemented during transport, import, and upon receipt to protect against the spread or introduction of disease.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate 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;

(2) Evaluate the accuracy of our estimate of the burden of the 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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 1.84 hours per response.

Respondents: Researchers, universities, research and development organizations, diagnostic laboratories, and other interested parties who possess, use, or transfer select agents or toxins.

Estimated annual number of respondents: 3,154.

Estimated annual number of responses per respondent: 1.

Estimated annual number of responses: 3,283.

Estimated total annual burden on respondents: 6,055 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request

for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 9th day of November 2021.

Jack Shere,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–24925 Filed 11–15–21; 8:45 am]

BILLING CODE 3410–34–P

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

Privacy Act of 1974; System of Records

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice; proposed new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, the Architectural and Transportation Barriers Compliance Board (Access Board or Board) is proposing to establish a new system of records titled, ''USAB.001—Reasonable Accommodation Records.'' This system of records covers records related to the administration, adjudication, and implementation of reasonable accommodation requests by agency employees and applicants for employment. The Office of Management and Budget has approved publication of this Notice after expedited review.

DATES: This Notice is effective on publication, with the exception of the routine uses. The routine uses will be effective 30 days after publication, unless comments are received that dictate otherwise. Written comments should be submitted December 16, 2021.

ADDRESSES: You may submit comments on this notice by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: privacy@access-board.gov.*
- *Mail:* Office of General Counsel, U.S. Access Board, 1331 F Street NW, Suite 1000, Washington, DC 20004–1111.

Instructions: All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Wendy Marshall, Attorney-Advisor and Privacy Officer, (202) 272–0043, *marshall@access-board.gov.*

SUPPLEMENTARY INFORMATION: The Access Board is publishing this notice to inform the public of the creation of a new system of records relating to accommodation requests from Access Board employees and applicants. Section 501 of the Rehabilitation Act of 1973 requires federal employers to provide reasonable accommodations to qualified individuals with disabilities who are employees or applicants, unless doing so would cause undue hardship. 29 U.S.C. 791. Similarly, Title VII of the Civil Rights Act of 1964 requires an employer, once on notice, to reasonably accommodate an employee whose sincerely-held religious belief, practice, or observance conflicts with a work requirement, unless providing the accommodation would create an undue hardship. 42 U.S.C. 2000e. Reasonable accommodations provide modifications or adjustments to: (1) The job application process; (2) the work environment; and/or (3) the manner in which a position is customarily performed. The proposed records system is necessary to allow the Access Board to collect and maintain records on employees or applicants who request reasonable accommodations based on either disability or sincerely-held religious belief, practice, or observance. Additionally, it will also enable the Board to track and report the processing of accommodation requests agency-wide to comply with applicable laws and regulations.

SYSTEM NAME:

USAB.001—Reasonable Accommodation Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

U.S. Access Board, 1331 F Street NW, Suite 1000, Washington, DC 20004.

SYSTEM MANAGER:

Director of Administration, U.S. Access Board, 1331 F Street NW, Suite 1000, Washington, DC 20004.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 29 U.S.C. 791 *et seq.;* 42 U.S.C. 12101 *et seq.;* 42 U.S.C. 2000e *et seq.;* 42 U.S.C. 2000bb *et seq.;* 44 U.S.C. 3101; 29 CFR 1605, 1614; Executive Order (E.).) 13164 (July 28, 2000); and E.O. 13548 (July 10, 2010).

PURPOSE(S) OF THE SYSTEM:

This system of records is intended to support the receipt, review, evaluation of requests made to the Access Board for reasonable accommodations (regardless of type of accommodation), the outcome of such requests, and the implementation of approved accommodations. Additionally, this record system is also intended to track and report the processing of requests for USAB-wide reasonable accommodations to comply with applicable laws and regulations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by this system include prospective, current, and former Access Board employees (including, but not limited to, full-time and part-time employees, temporary hires, interns, and co-op students.) who have requested reasonable accommodations.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name and employment information of current or prospective employee needing an accommodation; requester's name and contact information (if different than the employee who needs an accommodation); date request was initiated; information concerning the nature of the disability or religious belief, practice, or observance and the need for accommodation, including appropriate medical or other documentation; occupational series; pay grade; essential duties of the position; details of the accommodation request, such as: Type of accommodation requested, how the requested accommodation would assist in job or allow job performance while accommodating the disability or religious belief, practice, or observance; the sources of technical assistance consulted in trying to identify alternative reasonable accommodation; any additional information provided by the requester relating to the processing of the request; whether the request was approved or denied; whether the accommodation was approved for a trial period; and, documentation between the employee and his/her supervisor(s) regarding the accommodation.

RECORD SOURCE CATEGORIES:

Subject individuals; individual making the request (if different than the subject individuals); medical and equal employment opportunity professionals; and the subject individuals' supervisor(s).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, disclosures outside the agency may be made as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. Law Enforcement—In the event that a system of records maintained by the Access Board to carry out its functions indicates a violation or potential

violation of law, whether criminal, civil, or regulatory in nature, and whether arising by general statute or particular program pursuant thereto, the relevant records in the system of records may be disclosed to the appropriate agency, whether federal, state, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order issued pursuant thereto.

2. Disclosure When Requesting Information—A record from this system of records may be disclosed to a federal, state, or local agency or to another public or private source maintaining civil, criminal, or other relevant enforcement information or other pertinent information, if and to the extent necessary to obtain information relevant to an Access Board decision concerning the hiring or retention of an employee, personnel security (*e.g.,* suitability/fitness determinations), or the letting of a contract.

3. Disclosure of Existence of Record Information—With the approval of the Access Board Executive Director, the Director of Administration (or his or her designee), the fact that this system of records includes information relevant to a federal agency's decision in connection with the hiring or retention of an employee, personnel security (*e.g.,* suitability, fitness determinations), retention of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit may be disclosed to that federal agency.

4. Disclosure in Litigation—A record from this system of records may be disclosed in a proceeding before a court or other adjudicative body in which the Access Board, an employee of the Access Board in his or her official capacity, or an employee of the Access Board in his or her individual capacity if the Access Board (or the Department of Justice (''DOJ'')) has agreed to represent him or her is a party, or the United States or any other federal agency is a party and the Access Board determines that it has an interest in the proceeding, if the Access Board determines that the record is relevant to the proceeding and that the use is compatible with the purpose for which the Access Board collected the information.

5. Disclosure to the Department of Justice in Litigation—When the Access Board, an employee of the Access Board in his or her official capacity, or an employee of the Access Board in his or her individual capacity whom the Access Board has agreed to represent is a party to a proceeding before a court or other adjudicative body, or the United States or any other federal agency is a party and the Access Board determines that it has an interest in the proceeding, a record from this system of records may be disclosed to the DOJ if the Access Board is consulting with the DOJ regarding the proceeding or has decided that the DOJ will represent the Access Board, or its interest, in the proceeding and the Access Board determines that the record is relevant to the proceeding and that the use is compatible with the purpose for which the Access Board collected the information.

6. Congressional Inquiries—A record from this system of records may be disclosed to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

7. Disclosure in Response to a Federal Data Breach—A record from this system of records may be disclosed to appropriate agencies, entities, and persons when: (1) The Access Board suspects or has confirmed that there has been a breach of the system of records; (2) the Access Board as determined that, as a result of the suspected or confirmed breach, there is a risk of harm to individuals, the Board (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 Access Board efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

8. Contractors, Experts, and Consultants—To contractors, experts, consultants, and the agents of thereof, and others performing or working on a contract, service, cooperative agreement, or other assignment for the Access Board when necessary to accomplish an agency function. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to Access Board employees.

9. Records Management—To the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906.

10. Gathering Information—To any source from which information is requested in the course of processing a grievance, investigation, arbitration, or other litigation, to the extent necessary to identify the individual, inform the source of the purpose(s) of the request, and identify the type of information requested.

11. Disclosure to a Federal Agency—To disclose information to a Federal agency, in response to its request, in connection with hiring or retaining an employee, issuing a security clearance, conducting a security or suitability investigation of an individual, or classifying jobs, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

12. Assistance to Federal Agencies and Entities—To another Federal agency or Federal entity, when the Access Board determines that information from this system is reasonably necessary to assist the recipient agency or entity in: (a) Responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, program, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

13. Medical Providers—To physicians or other medical professionals to provide them with, or obtain from them, the necessary medical documentation and/or certification for reasonable accommodations.

14. Decisions Concerning Reasonable Accommodation—A record in this system of records may be disclosed, but only to the extent necessary, to individuals involved in processing a request for reasonable accommodation or in providing any accommodation granted, including medical professionals; agency counsel; individuals consulted outside of the Access Board, such as employees of the Equal Employment Opportunity Commission or other federal agencies concerning the Access Board's legal obligations; and vendors of assistive technology or other devices needed as accommodations.

15. Alternative Dispute Resolution—To appropriate third-parties contracted by the Access Board to facilitate mediation or other alternative dispute resolution procedures or programs.

16. Medical Emergency—To medical personnel to meet a bona fide medical emergency.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system consist of electronic and/or hard-copy (paper) records. Paper files are maintained in locked file cabinets. Electronic records are maintained in restricted access folders on the Access Board's internal, cloud-based General Support System

(GSS), which is Fed-RAMP compliant. Access is limited to the system owner(s) and other agency personnel who have an official need for access to perform their duties (*e.g.,* IT administrators, agency litigation counsel). Access Board policy requires new employees to read and acknowledge the rules of behavior applicable to all agency information technology systems (including appropriate protection and handling of personally identifiable information) before getting access to these systems and complete annual cybersecurity awareness training.

POLICIES AND PRACTITCES FOR RETRIEVAL OF RECORDS:

Records are retrievable by a variety of fields including, but not limited to, the individual's name, date of request, and nature of accommodation request. Records are typically retrieved by requester name.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Electronic and paper records are retained in accordance with the National Archives and Records Administration (NARA)'s General Records Schedule 2.3, Employee Relations Records, Item ## 020 (administrative program files) and 021 (employee case files), which prescribes a three-year retention period. For administrative program files, the retention period dates from file supersession. For employee case files the retention period dates from either employee separation from the agency or conclusion of any appeals, whichever is later. When eligible for destruction, electronic records are securely destroyed or erased using methods prescribed by the National Institute of Standards and Technology. Hard-copy records are permanently destroyed by shredding or burning.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to system records is restricted to authorized Access Board personnel who are system owners or have an official need to access such records to perform their duties. Electronic records are stored in restricted-access folders on the Access Board's internal, cloud-based GSS. Access to electronic records is controlled by technical safeguards through assignment of system roles and permissions, secure log-ins, time-out features, firewalls, and cybersecurity monitoring systems. Access Board policy also requires all emails, email strings, and attachments that contain sensitive personally identifiable information to be protected by encryption or password protection before transmission, absent express waiver from an agency privacy officer. Paper records are maintained in locked file cabinets with access limited to those personnel whose official duties require access. When paper records containing personally identifiable information are photocopied, faxed, or scanned, care is taken to ensure that no copies are left unattended where they could be viewed by unauthorized individuals.

RECORD ACCESS PROCEDURES:

Individuals seeking access to, or notification of, any record contained in this system of records, or seeking to contest its content, may inquire in writing in accordance with instructions appearing in the Access Board's Privacy Act Implementation rule, 36 CFR part 1121, which also appear on the Access Board's website at *www.access-board.gov/privacy.*

CONTESTING RECORD PROCEDURES:

See ''Record Access Procedures,'' above.

NOTIFICATION PROCEDURE:

See ''Record Access Procedures,'' above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Gretchen Jacobs,

General Counsel.

[FR Doc. 2021–24907 Filed 11–15–21; 8:45 am]

BILLING CODE 8150–01–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Spatial, Address, and Imagery Data Program

The Department of Commerce will submit the following information collection request 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. We invite 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. Public comments were previously requested via the **Federal Register** on Friday, July 29, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau, Commerce.

Title: Spatial, Address, and Imagery Data Program.

OMB Control Number: 0607–1008.

Form Number(s): None.

Type of Request: Regular submission, Request for an Extension of a Currently Approved Collection.

Number of Respondents: 1,500 (500/year).

Average Hours per Response: 2.5 hours.

Estimated Total Burden Hours: 3,750 (1,250/year). Please note, this figure was miscalculated in the 60-day **Federal Register** Notice. It has been corrected in this notice.

Needs and Uses: The Spatial, Address, and Imagery Data (SAID) Program is a voluntary geographic partnership programs that collects data to update and maintain the U.S. Census Bureau's geographic database of addresses, streets, and imagery known as the Master Address File/Topologically Integrated Geocoding and Referencing (MAF/TIGER) System. The MAF/TIGER System is vital for the Census Bureau's data collection, processing, tabulation, and dissemination programs for the United States and Puerto Rico.

The geographic framework within the MAF/TIGER System enables the Census Bureau field personnel to navigate to the appropriate locations for data collection. It enables the Census Bureau to define geographic boundaries, including census blocks, and accurately link demographic data from surveys and the decennial census to census blocks, locations, and areas, such as counties, cities, and school districts for data tabulation and dissemination.

The SAID Program supports the Census Bureau's ongoing demographic surveys and 2030 Census planning efforts by continuing to improve address coverage, collect and update street centerlines, and enhance the overall quality and integrity of the MAF/TIGER System after major Census update programs have concluded. The SAID Program provides the Census Bureau with a continuous method to obtain current, accurate, and complete address, street centerline, and imagery data.

Since its inception, the SAID Program has allowed the Census Bureau to update addresses and street centerlines across the country, with participation covering nearly 89 percent of the housing units in the nation. Moving forward, the SAID Program will

continue to acquire addresses, street centerlines, and imagery in areas targeted for housing unit growth or change to continue updating and improving the MAF/TIGER System.

The SAID Program follows the process below:

- The Census Bureau invites partners in targeted areas each fiscal year, including tribal, state, county, and local governments; federal agencies; and other authoritative organizations.
- Partners are asked to provide a current address list with associated location points and attributes, a street centerline file, and/or imagery data for their jurisdiction that is no more than two years old.
- Partners upload the requested data files using the Secure Web Incoming Module (SWIM), deliver large imagery datasets on hard drives, or the Census Bureau acquires the files/data though direct download.
- The Census Bureau validates, then updates the MAF/TIGER System with the address and street centerline data provided by partners and uses the provided imagery for quality control and change detection.
- The Census Bureau uses these updated addresses, streets, and imagery to support Census Bureau field operations, decennial census operations, ongoing demographic survey response collection, and data tabulation.
- The Census Bureau provides partners feedback regarding the data they supplied, including an appropriate thank you letter and a detailed, non-Title 13 address report and/or TIGER/Line shapefile.

Affected Public: Tribal, state, county, and local governments and organizations as well as other federal agencies.

Frequency: Annual.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. 16, 141, and 193.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

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 and entering either the title of the collection or the OMB Control Number 0607–1008.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–25010 Filed 11–15–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Order Denying Export Privileges; In the Matter of: Manuel Valencia-Hermosillo, 303 E South Mountain Avenue, Phoenix, AZ 85042

On October 13, 2017, in the U.S. District Court for the District of Arizona, Manuel Valencia-Hermosillo (''Valencia-Hermosillo'') was convicted of violating Section 38 of the Arms Export Control Act, 22 U.S.C. 2778 (2012) (''AECA''), by knowingly and willfully attempting to export and cause to be exported from the United States to Mexico, 11,000 rounds of Wolf 7.62 × 39mm ammunition; 100 Palmetto State Armory 5.56 rifle magazines; and 100 Korean 7.62 × 39 rifle magazines, all of which were designated as defense articles on the United States Munitions List, without the required U.S. Department of State licenses. Valencia-Hermosillo was sentenced to 15 months in prison with credit for time served, three years of supervised release, and an assessment of $100. Valencia-Hermosillo has been placed on the U.S. Department of State debarred list.

The Export Administration Regulations (''EAR'' or ''Regulations'') are administered and enforced by the U.S. Department of Commerce's Bureau of Industry and Security (''BIS'').[1]

Section 766.25 of the Regulations provides, in pertinent part, that the ''Director of [BIS's] Office of Export Enforcement, in consultation with the Director of [BIS's] Office of Exporter Services, may deny the export privileges of any person who has been convicted of a violation of any of the statues set forth at 50 U.S.C. 4819 (e)(1)(B),'' [2] including Section 38 of the AECA. 15 CFR 766.25(a).[3] The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d). In addition, pursuant to Section 750.8 of the Regulations, BIS's Office of Exporter Services may revoke any BIS-issued licenses in which the person has an interest at the time of his/her conviction.[4]

BIS received notice of Valencia-Hermosillo's conviction for violating Section 38 of the AECA, and pursuant to Section 766.25 of the Regulations, has provided notice and an opportunity for Valencia-Hermosillo to make a written submission to BIS. BIS has not received a written submission from Valencia-Hermosillo.

Based upon my review of the record and consultations with BIS's Office of Exporter Services, including its Director, and the facts available to BIS, I have decided to deny Valencia-Hermosillo's export privileges under the Regulations for a period of seven years from the date of Valencia-Hermosillo's conviction. The Office of Exporter Services has also decided to revoke any BIS-issued license in which Valencia-Hermosillo had an interest at the time of his conviction.

Accordingly, it is hereby *ordered:First*, from the date of this Order until October 13, 2024, Manuel Valencia-Hermosillo, with a last known address of 303 E. South Mountain Avenue, Phoenix, AZ 85042, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives (''the Denied

[1] The Regulations are currently codified in the Code of Federal Regulations at 15 CFR parts 730–774 (2021). The Regulations originally issued under the Export Administration Act of 1979, as amended, 50 U.S.C. 4601–4623 (Supp. III 2015) (''EAA''), which lapsed on August 21, 2001. The President, through Executive Order 13,222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which was extended by successive Presidential Notices, continued the Regulations in full force and effect under IEEPA. On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. 4801–4852 (''ECRA''). While Section 1766 of ECRA repeals the provisions of the EAA (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all rules and regulations that were made or issued under the EAA, including as continued in effect pursuant to IEEPA, and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA.

[2] The Director, Office of Export Enforcement, is now the authorizing official for issuance of denial orders, pursuant to recent amendments to the Regulations (85 FR 73411, November 18, 2020).

[3] As codified at the time of the underlying conviction at issue, Section 11(h)(1) of the EAA, as amended, provided that: ''No person convicted of a violation of this chapter (or any regulation, license, or order issued under this chapter), any regulation, license, or order issed under the International Emergnecy Economic Powers Act [50 U.S.C. 1701, *et seq.*], section 793, 794 or 798 of title 18, section 783(b) of this title, or section 2778 of title 22 shall be eligible, at the discretion of the Secretary, to apply for or use any export license under this chapter for a period of up to 10 years from the date of conviction. The Secretary may revoke any export license under this chapter in which such person has an interest at the time of conviction.'' 50 U.S.C. 4610(h)(1).

[4] *See* notes 1 and 3, *supra.*

Person''), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23of the Regulations, any other person, firm, corporation, or business organization relatedto Valencia-Hermosillo by ownership, control, position of responsibility, affiliation, orother connection in the conduct of trade or business may also be made subject to theprovisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Valencia-Hermosillo may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to Valencia-Hermosillo and shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until October 13, 2024.

John Sonderman,

Director, Office of Export Enforement.

[FR Doc. 2021–24910 Filed 11–15–21; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Requirements for Approved Construction Investments

The Department of Commerce will submit the following information collection request 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. We invite 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. Public comments were previously requested via the **Federal Register** on September 3, 2021, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Economic Development Administration (EDA), Commerce.

Title: Requirements for Approved Construction Investments.

OMB Control Number: 0610–0096.

Form Number(s): None.

Type of Request: Revision and extension of a currently approved information collection.

Number of Respondents: 3,500.

Average Hours per Response: 2 hours.

Burden Hours: Hours: 7,000 hours.

Needs and Uses: To effectively administer and monitor its economic development assistance programs, EDA collects certain information from applicants for, and recipients of, EDA investment assistance. EDA may award assistance for construction projects through its Public Works and Economic Adjustment Assistance (EAA) programs. Public Works program investments help support the construction or rehabilitation of essential public infrastructure and facilities necessary to generate or retain private sector jobs and investments, attract private sector capital, and promote vibrant economic ecosystems, regional competitiveness, and innovation. The EAA program provides a wide range of technical, planning, and infrastructure assistance in regions experiencing adverse economic changes that may occur suddenly or over time.

EDA proposes to revise and extend the checklists and templates that constitute EDA's post-approval tool for construction projects. None of the edits are expected to increase the time burden on the respondent nor do the modifications change the type of information collected.

Affected Public: Recipients of EDA construction (Public Works or EAA) awards, including (1) cities or other political subdivisions of a State, including a special purpose unit of State or local government engaged in economic or infrastructure development activities, or a consortium of political subdivisions; (2) States; (3) institutions of higher education or a consortium of institutions of higher education; (4) public or private non-profit organizations or associations; (5) District Organizations; and (6) Indian Tribes or a consortia of Indian Tribes.

Frequency: As needed during the period of performance of financial assistance awards for construction projects.

Respondent's Obligation: Mandatory.

Legal Authority: The Public Works and Economic Development Act of 1965 (42 U.S.C. 3121 *et seq.*).

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

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 and entering either the title of the collection or the OMB Control Number 0610–0096.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–24935 Filed 11–15–21; 8:45 am]

BILLING CODE 3510–24–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–952, A–583–844]

Narrow Woven Ribbons With Woven Selvedge From the People's Republic of China and Taiwan: Final Results of the Expedited Sunset Reviews of the Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of these expedited sunset reviews, the Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) orders on narrow woven ribbons with woven selvedge from the People's Republic of China (China) and Taiwan would likely lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable November 16, 2021.

FOR FURTHER INFORMATION CONTACT: Reginald Anadio, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3166.

SUPPLEMENTARY INFORMATION:

Background

On August 2, 2021, Commerce published the notice of initiation of the sunset reviews of the *AD Orders* [1] pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] In accordance with 19 CFR 351.218(d)(1)(i) and (ii), Commerce received notices of intent to participate in these sunset reviews from Berwick Offray LLC and its wholly owned subsidiary, Lion Ribbon Company LLC (collectively, the domestic interested party), within 15 days after the date of publication of the *Initiation Notice*.[3] The domestic interested party claimed interested party status under section 771(9)(C) of the Act.

Commerce received adequate substantive responses to the *Initiation Notice* from the domestic interested party within the 30-day period specified in 19 CFR 351.218(d)(3)(i).[4] Commerce received no substantive responses from any respondent interested parties. On September 20, 2021, Commerce notified the U.S. International Trade Commission that we did not receive an adequate substantive response from respondent interested parties.[5] In accordance with section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted expedited, *i.e.,* 120-day, sunset reviews of the *AD Orders.*

Scope of the AD Orders

The products subject to the *AD Orders* are narrow woven ribbons with woven selvedges, and are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 5806.32.1020; 5806.32.1030; 5806.32.1050 and 5806.32.1060. Subject merchandise also may enter under subheadings 5806.31.00; 5806.32.20; 5806.39.20; 5806.39.30; 5808.90.00; 5810.91.00; 5810.99.90; 5903.90.10; 5903.90.25; 5907.00.60; and 5907.00.80 and under statistical categories 5806.32.1080; 5810.92.9080; 5903.90.3090; and 6307.90.9889. The HTSUS numbers are provided for convenience and customs purposes. A full description of the scope of the *AD Orders* is contained in the Issues and Decision Memorandum.[6] The written description is dispositive.

Analysis of Comments Received

All issues raised in this review are addressed in the Issues and Decision Memorandum, including the likelihood of continuation or recurrence of dumping in the event of revocation of the *AD Orders* and the magnitude of dumping margins likely to prevail if the *AD Orders* were revoked. A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in the Issues and Decision Memorandum, which 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 Issues and Decision Memorandum can be found at *https://access.trade.gov/public/FRNotices ListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c) and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *AD Orders* would be likely to lead to continuation or recurrence of dumping and the magnitude of the margins of dumping likely to prevail would be weighted-average margins up to the following percentages:

Country	Weighted-average margin (percent)
China	247.65
Taiwan	4.37

Notification Regarding Administrative Protective Orders

This notice serves as a 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). Timely written notification of the destruction of APO materials or conversion to judicial

[1] *See Notice of Antidumping Duty Orders: Narrow Woven Ribbons With Woven Selvedge from Taiwan and the People's Republic of China: Antidumping Duty Orders,* 75 FR 53632 (September 1, 2010), as amended in *Narrow Woven Ribbons With Woven Selvedge from Taiwan and the People's Republic of China: Amended Antidumping Duty Orders,* 75 FR 56982 (September 17, 2010) (collectively, *AD Orders*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 86 FR 41439 (August 2, 2021) (*Initiation Notice*).

[3] *See* Domestic Interested Party's Letter, ''Narrow Woven Ribbons with Woven Selvedge from the People's Republic of China: Notice of Intent to Participate in Sunset Review,'' dated August 17, 2021; *see also* Domestic Interested Party's Letter, ''Narrow Woven Ribbons with Woven Selvedge from Taiwan: Notice of Intent to Participate in Sunset Review,'' dated August 17, 2021.

[4] *See* Domestic Interested Party's Letter, ''Narrow Woven Ribbons with Woven Selvedge from the People's Republic of China: Substantive Response to the Notice of Initiation of Sunset Review,'' dated September 1, 2021; *see also* Domestic Interested Party's Letter, ''Narrow Woven Ribbons with Woven Selvedge from Taiwan: Substantive Response to the Notice of Initiation of Sunset Review,'' dated September 1, 2021.

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on August 2, 2021,'' dated September 20, 2021.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Expedited Sunset Reviews of the Antidumping Duty Orders on Narrow Woven Ribbons with Woven Selvedge from the People's Republic of China and Taiwan,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

Commerce is issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.221(c)(5)(ii).

Dated: November 9, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, Performing the Nonexclusive Functions and Duties of The Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Orders
IV. History of the Orders
V. Legal Framework
VI. Discussion of the Issues
VII. Final Results of Expedited Sunset Reviews
VIII. Recommendation

[FR Doc. 2021–24961 Filed 11–15–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

United States Travel and Tourism Advisory Board: Meeting of the United States Travel and Tourism Advisory Board

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The United States Travel and Tourism Advisory Board (Board or TTAB) will hold a meeting on Friday, December 3, 2021. The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry. The purpose of the meeting is for Board members to discuss and potentially adopt recommendations for the Secretary in the areas of (1) top issues facing the sector related to climate change and (2) actions to provide for employment in the sector. The final agenda will be posted on the Department of Commerce website for the Board at *https://www.trade.gov/ttab-meetings* at least two days prior to the meeting.

DATES: Friday, December 3, 2021, 2:00 p.m.–3:00 p.m. EST. The deadline for members of the public to register for the meeting or to submit written comments for dissemination prior to the meeting is 5:00 p.m. EST on Wednesday, December 1, 2021.

ADDRESSES: The meeting will be held virtually. The access information will be provided by email to registrants. Requests to register (including to speak or for auxiliary aids) and any written comments should be submitted by email to *TTAB@trade.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer Aguinaga, the United States Travel and Tourism Advisory Board, National Travel and Tourism Office, U.S. Department of Commerce; telephone: 202–482–2404; email: *TTAB@trade.gov.*

SUPPLEMENTARY INFORMATION: *Public Participation:* The meeting will be open to the public and will be accessible to people with disabilities. Any member of the public requesting to join the meeting is asked to register in advance by the deadline identified under the **DATES** caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted but may not be possible to fill. There will be fifteen (15) minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for public comments may be limited to three (3) minutes per person. Members of the public wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name and address of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. EST on Wednesday, December 1, 2021, for inclusion in the meeting records and for circulation to the members of the Board.

In addition, any member of the public may submit pertinent written comments concerning the Board's affairs at any time before or after the meeting. Comments may be submitted to Jennifer Aguinaga at the contact information indicated above. To be considered during the meeting, comments must be received no later than 5:00 p.m. EST on Wednesday, December 1, 2021, to ensure transmission to the Board prior to the meeting. Comments received after that date and time will be transmitted to the Board but may not be considered during the meeting. Copies of Board meeting minutes will be available within 90 days of the meeting.

This Notice is published pursuant to the Federal Advisory Committee Act, as amended (FACA), 5 U.S.C., app., 9(c). It has been determined that the Committee is necessary and in the public interest. The Committee was established pursuant to Commerce's authority under 15 U.S.C. 1512, established under the FACA, as amended, 5 U.S.C. App., and with the concurrence of the General Services Administration.

Jennifer Aguinaga,

Designated Federal Officer, United States Travel and Tourism Advisory Board.

[FR Doc. 2021–24891 Filed 11–15–21; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Baldrige Executive Fellow Program

AGENCY: National Institute of Standards and Technology (NIST), 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 January 18, 2022.

ADDRESSES: Interested persons are invited to submit written comments by mail to Maureen O'Reilly, Management Analyst, NIST by email to *PRAcomments@doc.gov.* Please reference OMB Control Number 0693–0076 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 Dawn Bailey, Baldrige Performance Excellence Program, NIST, 100 Bureau Drive, Stop

1020, Gaithersburg, MD 20899, 301–975–3074, *dawn.bailey@nist.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Baldrige Performance Excellence Program seeks applicants for the Baldrige Executive Fellows Program, a one-year, leadership development experience for direct reports to the most senior leader in an organization or business unit leaders. Using the Baldrige Excellence Framework as a foundation, the program discusses impactful leadership through visits to Baldrige Award recipient sites and senior leaders, virtual discussions, and face-to-face peer training using an adult learning model. Fellows will discuss how to achieve performance excellence for their own organizations, stimulate innovation, and build the knowledge and capabilities necessary for organizational sustainability. Fellows will create a capstone project that tackles an issue of strategic importance in their own organizations; capstones have included innovating supply chains and customer relationship management systems, improving health systems and their communication with physicians, and creating balanced scorecards. The Baldrige Executive Fellows Program has been nationally recognized as a leading executive-development program as part of the leadership awards, sponsored by *HR.com*. The program is aligned with the Baldrige Program mission to improve the competitiveness and performance of U.S. organizations for the benefit of all U.S. residents. The Baldrige Program and its Malcolm Baldrige National Quality Award were created by Public Law 100–107 (The Malcolm Baldrige National Quality Improvement Act of 1987) and signed into law on August 20, 1987.

II. Method of Collection

Senior leaders interested in applying for selection as a Baldrige Fellow must provide the following package of material directly to the Baldrige Program:

1. A resumé, including email, postal address, and telephone contact information; and the name and email address of an assistant or alternate contact person.

2. An organizational chart that includes names and titles showing the applicant's position within the organization.

3. A recommendation letter from the applicant's highest-ranking official showing the organization's support of his/her participation in the program.

4. A list of key competitors (in order that the Baldrige Program may avoid creating a cohort that would be unable to share effectively due to competitive situations).

U.S. mail or other delivery service is one way to provide materials. Another secure way to provide materials is through the NIST Secure File Transfer Service (''N-files''). Information is collected one time per year (typically in September–December) for each cohort of Fellows.

Information is needed to make selection decisions that are based on (1) sector mix, (2) appropriate level within the organization, (3) likelihood to follow through, (4) diversity, and (5) no direct competitors with participating award recipients or other Fellows.

III. Data

OMB Control Number: 0693–0076.

Form Number(s): None.

Type of Review: Regular submission, extension of a current information collection.

Affected Public: Any senior or mid-level leader from business or other for-profit organizations; not-for-profit institutions; state, local, or tribal government; Federal government.

Estimated Number of Respondents: 24 per year.

Estimated Time per Response: 1 hour to gather materials.

Estimated Total Annual Burden Hours: 24 hours.

Estimated Total Annual Cost to Public: $0.

Respondent's Obligation: Voluntary.

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 Chief Information Officer, Commerce Department.

[FR Doc. 2021–24955 Filed 11–15–21; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB570]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Surfclam and Ocean Quahog Committee and Advisory Panel will hold a joint, public meeting.

DATES: The meeting will be held on Monday, December 6, 2021, from 9:30 a.m. to 12 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held via webinar. Connection information will be posted to the Council's calendar prior to the meeting at *www.mafmc.org.*

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Mid-Atlantic Fishery Management Council's Surfclam and Ocean Quahog Committee and Advisory Panel will meet together, via webinar on Monday, December 6, 2021, from 9:30 a.m. until 12 p.m. The purpose of this meeting is to review and discuss the draft document being prepared for the Council to address issues related to the species separation requirements in the Atlantic surfclam and ocean quahog fisheries. The Committee may develop recommendations for next steps related to this issue, to be presented to the full Council at their December meeting.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shelley Spedden, (302) 526–5251 at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 9, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–24899 Filed 11–15–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB582]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a joint public meeting of its Scallop Committee via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Friday, December 3, 2021, at 9 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/5448562120551399437.*

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee will discuss Framework 34 (FW 34): Review specifications alternatives in FW 34 and make final recommendations. FW 34 will set specifications including acceptable biological catch/annual catch limit (ABC/ACLs), days-at-sea (DAS), access area allocations for Limited Access (LA) and Limited Access General Category (LAGC), Total Allowable Landings (TAL) for Northern Gulf of Maine (NGOM) management area, target-TAC for LAGC incidental catch and set-asides for the observer and research programs for fishing year 2022 and default specifications for fishing year 2023. Also on the agenda is Evaluation of Rotational Management: Review draft report and provide feedback. They will also receive an update on progress from the Scallop Survey Working Group. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 9, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–24898 Filed 11–15–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB586]

South Atlantic Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce

ACTION: Notice of public meetings.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold meetings of the following: Mackerel Cobia Committee; Snapper Grouper Committee; Southeast Data, Assessment and Review (SEDAR) Committee; Citizen Science Committee; and Outreach and Communications Committee. The meeting week will also include a formal public comment session and a meeting of the Full Council (partially Closed Session).

DATES: The Council meeting will be held from 8:30 a.m. on Monday, December 6, 2021, until 12 p.m. on Friday, December 10, 2021.

ADDRESSES: *Meeting address:* The meeting will be held at the Beaufort Hotel, 2400 Lennoxville Road, Beaufort, NC 28516; phone: (252) 728–3000. The meeting will also be available via webinar. Registration is required. See **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 302–8440 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION:

Meeting information, including agendas, overviews, and briefing book materials will be posted on the Council's website at: *http://safmc.net/safmc-meetings/council-meetings/.* Webinar registration links for the meeting will also be available from the Council's website.

Public comment: Public comment on agenda items may be submitted through the Council's online comment form available from the Council's website at: *http://safmc.net/safmc-meetings/council-meetings/.* Comments will be accepted from November 19, 2021, until December 10, 2021. These comments are accessible to the public, part of the Administrative Record of the meeting, and immediately available for Council consideration.

The items of discussion in the individual meeting agendas are as follows:

Council Session I, Monday, December 6, 2021, 8:30 a.m. Until 10 a.m. (Closed Session) and 10 a.m.–12 p.m.

The Council will review applications for open seats on its advisory panels and the Socio-Economic Sub-panel of its Scientific and Statistical Committee. Participants for the SEDAR 82 assessment addressing South Atlantic Triggerfish and for the SEDAR 76 assessment for South Atlantic Black Sea Bass will also be reviewed and approved. The Council will receive a legal briefing if needed.

The Council will then meet in Open Session to receive reports from state agencies, Council liaisons, NOAA Office of Law Enforcement, and the U.S. Coast Guard. The Council will receive an update on the review of Standardized

Bycatch Reporting Methodology (SBRM) in Council Fishery Management Plans from NOAA Fisheries and recommendations on SBRM from its Scientific and Statistical Committee (SSC). Council members will review any Exempted Fishery Permit applications and additional topics as needed.

Mackerel Cobia Committee, Monday, December 6, 2021, 1:30 p.m. Until 5 p.m.

The Committee will review public hearings comments received for Coastal Migratory Pelagics (CMP) Amendment 34 addressing management measures for Atlantic king mackerel and Spanish mackerel in the South Atlantic and continue work on the amendment. The Committee will also review public hearing input received on CMP Amendment 32 addressing management measures to end overfishing for Gulf of Mexico cobia and is scheduled to recommend approval of the amendment for Secretarial review. The Committee will also review management options for draft CMP Amendment 33 addressing Gulf migratory group king mackerel.

Snapper Grouper Committee, Tuesday, December 7, 2021, 8:30 a.m. Until 5:30 p.m. and Wednesday, December 8, 2021, 8:30 a.m. Until 3:45 p.m.

The Committee will receive a presentation on the Ecopath Project on Red Snapper Recruitment including modelling team discussion and SSC comments. The Committee will discuss possible revisions to management of the Snapper Grouper fishery including framework options and items to consider for long-term management, and consider input from its Snapper Grouper Advisory Panel (AP) and the Private Recreational Reporting Workgroup. The Committee will also review a white paper on South Atlantic Snapper Grouper Commercial Fishing Permits and consider recommendations from the Snapper Grouper AP.

The Committee will receive a presentation from NOAA Fisheries Southeast Fisheries Science Center on the SEDAR 68 Scamp Research Track Assessment and review SSC recommendations. The Committee will review options and recommendations from the Snapper Grouper AP for the following draft amendments to the Snapper Grouper Fishery Management Plan (FMP): Amendment 51 addressing snowy grouper; Amendment 52 addressing golden tilefish; and Amendment 53 addressing gag, and is scheduled to approve the amendments for public scoping.

The Committee will also review proposed modifications to greater amberjack management through Amendment 49 to the Snapper Grouper FMP and is scheduled to approve the amendment for public hearings. The Committee will review public scoping comments and recommendations from the Snapper Grouper AP for Snapper Grouper Amendment 44 addressing yellowtail snapper management measures and continue work on Snapper Grouper Amendment 50 with modifications to red porgy management. The Committee will receive updates on projects for the South Atlantic Red Snapper Count and the Greater Amberjack Count in the Gulf of Mexico and South Atlantic, and review any additional recommendations from the Snapper Grouper AP.

Formal Public Comment, Wednesday, December 8, 2021, 4 p.m.—Public comment will be accepted from individuals attending the meeting on all items on the Council meeting agenda. The Council Chair will determine the amount of time provided to each commenter based on the number of individuals wishing to comment.

Council Session II, Thursday, December 9, 2021, 8 a.m. Until 9 a.m. (Closed Session)

The Council will meet in Closed Session to conduct an annual performance review of its Executive Director.

SEDAR Committee, Thursday, December 9, 2021, 9 a.m. Until 11 a.m.

The Committee will receive a report from the SEDAR Steering Committee and consider revisions to current Council processes and approvals relative to stock assessments due to changes in SEDAR. The Committee will review the Terms of Reference and schedules for the following: SEDAR 68 Scamp Operational Assessment; SEDAR 82 Gray Triggerfish Research Track Assessment; SEDAR 83 Vermillion Snapper Operational Assessment; and the SEDAR 86 Red Grouper Operational Assessment. The Committee will also review the 2024 golden Tilefish Operational Statement of Work and address stock assessment prioritization.

Citizen Science Committee, Thursday, December 9, 2021, 11 a.m. Until 12 p.m.

The Committee will receive an update on the Council's Citizen Science Program and the program's research priorities and consider approving for adoption.

Outreach and Communications Committee, Thursday, December 9, 2021, 1:30 p.m. Until 3 p.m.

The Committee will receive a report from the Outreach and Communications AP, receive an update on the status of the Sea Grant Fellowship for outreach, and receive a demonstration of the Council's new website.

Council Session III, Thursday, December 9, 2021, From 3 p.m. Until 5:30 p.m., and Friday, December 10, 2021, 8:30 a.m. Until 12 p.m.

The Council will present the 2020 Law Enforcement Officer of the Year Award, discuss any applications for Exempted Fishery Permits, consider any legal briefing, and any SSC recommendations not covered earlier, if needed. The Council will receive staff reports, a briefing on the Kitty Hawk Offshore Wind Project, and review the FMP workplan and upcoming meetings. The Committee will receive reports from earlier Council sessions and reports from the following committees: Mackerel Cobia; Snapper Grouper; SEDAR, Citizen Science, and Outreach and Communications. The Council will also receive a report from the November 2021 meeting of its Executive Committee.

The Council will receive reports from NOAA Fisheries Southeast Fisheries Science Center including an update on commercial e-logbook progress and from the Southeast Regional Office, including updates on the Southeast For-Hire Electronic Reporting Program, SAFE Report status, a protected resources update, and a blueline tilefish summary.

The Council will discuss other business, upcoming meetings, and take action as necessary.

Documents regarding these issues are available from the Council office (see **ADDRESSES**).

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are 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: November 10, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–24963 Filed 11–15–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB581]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a joint public meeting of its Scallop Advisory Panel via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Thursday, December 2, 2021, at 9 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/9136197676274751757.*

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Advisory Panel will discuss Framework 34 (FW 34): Review specifications alternatives in FW 34 and make final recommendations. FW 34 will set specifications including acceptable biological catch/annual catch limit (ABC/ACLs), days-at-sea (DAS), access area allocations for Limited Access (LA) and Limited Access General Category (LAGC), Total Allowable Landings (TAL) for Northern Gulf of Maine (NGOM) management area, target-TAC for LAGC incidental catch and set-asides for the observer and research programs for fishing year 2022 and default specifications for fishing year 2023. Also on the agenda is Evaluation of Rotational Management: Review draft report and provide feedback. They will also receive an update on progress from the Scallop Survey Working Group. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 9, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–24890 Filed 11–15–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB587]

Western Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold its 142nd Scientific and Statistical Committee (SSC), Executive and Budget Standing Committee, and 189th Council meetings to take actions on fishery management issues in the Western Pacific Region.

DATES: The meetings will be held between November 30 and December 9, 2021. For specific times and agendas, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The meetings will be held by web conference via Webex. Instructions for connecting to the web conference and providing oral public comments will be posted on the Council website at *www.wpcouncil.org.* For assistance with the web conference connection, contact the Council office at (808) 522–8220.

The Council has arranged host sites only for the 189th Council meeting at the following venues: Cliff Pointe, 304 W. O'Brien Drive, Hagatna, Guam; BRI Building Suite 205, Kopa Di Oru St., Garapan, Saipan, Commonwealth of the Northern Mariana Islands (CNMI); and, Tedi of Samoa Building Suite 208B, Fagatogo Village, American Samoa.

FOR FURTHER INFORMATION CONTACT: Contact Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council; phone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: All times shown are in Hawaii Standard Time. The 142nd SSC meeting will be held between 11 a.m. and 5 p.m. on November 30–December 2, 2021. The Executive and Budget Standing Committee meeting will be held between 3 p.m. and 5 p.m. on December 6, 2021. The 189th Council meeting will be held between 11 a.m. and 5 p.m. on December 7–9, 2021.

Please note that the evolving public health situation regarding COVID–19 may affect the conduct of the December Council and its associated meetings. At the time this notice was submitted for publication, the Council anticipated convening the meeting by web conference with host site locations in Guam, CNMI and American Samoa for the 189th Council meeting only. Council staff will monitor COVID–19 developments and will determine the extent to which in-person public participation at host sites will be allowable consistent with applicable local and federal safety and health guidelines. If public participation will be limited to web conference only or on a first-come-first-serve basis consistent with applicable guidelines, the Council will post notice on its website at *www.wpcouncil.org.*

Agenda items noted as ''Final Action'' refer to actions that may result in Council transmittal of a proposed fishery management plan, proposed plan amendment, or proposed regulations to the U.S. Secretary of Commerce, under Sections 304 or 305 of the MSA. In addition to the agenda items listed here, the Council and its advisory bodies will hear

recommendations from Council advisors. An opportunity to submit public comment will be provided throughout the agendas. The order in which agenda items are addressed may change and will be announced in advance at the Council meeting. The meetings will run as late as necessary to complete scheduled business.

Background documents for the 189th Council meeting will be available at *www.wpcouncil.org.* Written public comments on final action items at the 189th Council meeting should be received at the Council office by 5 p.m. HST, December 3, 2021, and should be sent to Kitty M. Simonds, Executive Director; Western Pacific Fishery Management Council, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813, phone: (808) 522–8220 or fax: (808) 522–8226; or email: *info@wpcouncil.org.* Written public comments on all other agenda items may be submitted for the record by email throughout the duration of the meeting. Instructions for providing oral public comments during the meeting will be posted on the Council website. This meeting will be recorded (audio only) for the purposes of generating the minutes of the meeting.

Agenda for the 142nd SSC Meeting

Tuesday, November 30, 2021, 11 a.m. to 5 p.m.

1. Introductions
2. Approval of Draft Agenda and Assignment of Rapporteurs
3. Status of the 141st SSC Meeting Recommendations
4. Pacific Islands Fisheries Science Center (PIFSC) Director Report
5. Program Planning and Research
   - A. Report on the Territorial Creel Survey Expansion
   - B. Report on the Center for Independent Experts (CIE) Review of the Territorial Creel Survey Expansion
   - C. Improving Collaboration Between Stakeholders: Territorial Bottomfish Stock Assessment in the Pacific Islands
   - D. Report on the American Samoa Bottomfish Data Workshop with the Department of Marine and Wildlife Resources (DMWR)
   - E. SSC Working Group Report on American Samoa Bottomfish Data Evaluation
   - F. Council Coordination Committee (CCC) Reports
   - 1. Area-Based Management Working Group
   - 2. Environmental Justice
   - G. Public Comment
   - H. SSC Discussion and Recommendations
6. Protected Species
   - A. Hawaii Longline Fishery Seabird Mitigation Measures
   - 1. Modification of Seabird Interaction Mitigation Measures in the Deep-Set Longline Fishery (Action Item)
   - 2. Hawaii Shallow-Set Longline Fishery Experimental Fishing Permit
   - B. False Killer Whale Issues
   - 1. Report of the False Killer Whale Weak Hook Study
   - 2. Hawaii Longline Acoustic Monitoring Study
   - 3. Take Reduction Plan Research Priorities
   - C. Endangered Species Act (ESA) Consultations for the Hawaii Deep-set Longline Fishery, American Samoa Longline Fishery, and Bottomfish Fisheries
   - D. ESA and Marine Mammal Protection Act (MMPA) Updates
   - E. Public Comment
   - F. SSC Discussion and Recommendations

Wednesday, December 1, 2021, 11 a.m. to 5 p.m.

7. Pelagic and International Fisheries
   - A. American Samoa Longline Fishery Report
   - B. Hawaii Longline Fishery Report
   - C. Hawaii Community Tagging Program
   - D. Horizontal Movements, Utilization Distributions, and Mixing Rates of Yellowfin Tuna
   - E. SSC Working Group on Area-Based Management
   - F. International Fisheries
   - 1. South Pacific Regional Fishery Management Organization Science Committee
   - 2. 18th Western and Central Pacific Fisheries Commission (WCPFC) Regular Session
   - G. Public Comment
   - H. SSC Discussion and Recommendations

Thursday, December 2, 2021, 11 a.m. to 5 p.m.

8. Other Business
   - A. March 15–17, 2022 SSC Meeting Dates
9. Summary of SSC Recommendations to the Council

Agenda for the Executive and Budget Standing Committee

Monday, December 6, 2021, 3 p.m. to 5 p.m.

1. Financial Reports
2. Administrative Reports
3. Fall CCC Report
   - A. Area-Based Management Working Group
   - B. Environmental Justice
4. Council Programs
5. Council Family Changes
6. Meetings and Workshops
7. Other Issues
8. Public Comment
9. Discussion and Recommendations

Agenda for the 189th Council Meeting

Tuesday, December 7, 2021, 11 a.m. to 5 p.m.

1. Welcome and Introductions
2. Approval of the 189th Agenda
3. Approval of the 187th and 188th Meeting Minutes
4. Executive Director's Report
5. Agency Reports
   - A. NMFS
   - 1. Pacific Islands Regional Office
   - 2. PIFSC
   - B. NOAA Office of General Counsel Pacific Islands Section
   - C. Enforcement
   - 1. U.S. Coast Guard
   - 2. NOAA Office of Law Enforcement
   - 3. NOAA Office of General Counsel Enforcement Section
   - D. U.S. State Department
   - E. U.S. Fish and Wildlife Service
   - F. Public Comment
   - G. Council Discussion and Action
6. Program Planning and Research
   - A. National Legislative Report
   - B. Report on the Territorial Creel Survey Expansion
   - C. Report on the CIE Review of the Territorial Creel Survey Expansion
   - D. Improving Collaboration Between Stakeholders: Territorial Bottomfish Stock Assessment in the Pacific Islands
   - E. Regional Communications and Outreach Report
   - F. Advisory Group Report and Recommendations
   - 1. Advisory Panel (AP)
   - 2. Fishing Industry Advisory Committee (FIAC)
   - 3. Non-Commercial Fishing Advisory Committee (NCFAC)
   - 4. Social Science Planning Committee
   - 5. SSC
   - G. Public Comment
   - H. Council Discussion and Action

Tuesday, December 7, 2021, 4:30 p.m. to 5 p.m.

Public Comment on Non-Agenda Items

Wednesday, December 8, 2021, 11 a.m.–5 p.m.

7. Mariana Archipelago
   - A. Guam
   - 1. Department of Agriculture/Division Aquatic and Wildlife Resources Report

2. Isla Informe
3. The Pacific Community (SPC) Regional Technical Meeting on Coastal Fisheries and Aquaculture

B. CNMI
1. Arongol Falú
2. Department of Lands Natural Resources/Division of Fish and Wildlife Report

C. Advisory Group Report and Recommendations
1. AP
2. FIAC
3. NCFAC
4. SSC

D. Public Comment
E. Council Discussion and Action

8. American Samoa Archipelago
A. Motu Lipoti
B. DMWR Report
C. Report on the American Samoa Bottomfish Data Workshop with DMWR
D. SSC Report on the American Samoa Bottomfish Data Evaluation
E. SPC Regional Technical Meeting on Coastal Fisheries and Aquaculture
F. Advisory Group Report and Recommendations
1. AP
2. FIAC
3. NCFAC
4. SSC

G. Public Comment
H. Council Discussion and Action

9. Protected Species
A. Hawaii Longline Fishery Seabird Mitigation Measures
1. Modification of Seabird Interaction Mitigation Measures in the Deep-Set Longline Fishery (Final Action)
2. Hawaii Shallow-Set Longline Fishery Experimental Fishing Permit

B. False Killer Whale Issues
1. Report of the False Killer Whale Weak Hook Study
2. Hawaii Longline Acoustic Monitoring Study

C. ESA Consultations for the Hawaii Deep-Set Longline Fishery, American Samoa Longline Fishery, and Bottomfish Fisheries
D. ESA and MMPA Updates
E. Advisory Group Report and Recommendations
1. AP
2. FIAC
3. NCFAC
4. SSC

F. Public Comment
G. Council Discussion and Action

Thursday, December 9, 2021, 11 a.m.–5 p.m.

10. Pelagic and International Fisheries
A. American Samoa Longline Fishery Report
B. Hawaii Longline Fishery Report
C. Hawaii Community Tagging Program
D. Area-Based Management Working Group Reports
1. CCC Working Group
2. SSC Working Group

E. International Fisheries
1. WCPFC 17th Technical and Compliance Committee
2. WCPFC 17th Northern Committee Report
3. Permanent Advisory Committee
4. South Pacific Albacore Management Issues
5. Outcome of WCPFC 18th Regular Session

F. Advisory Group Report and Recommendations
1. AP
2. FIAC
3. NCFAC
4. SSC

G. Pelagic and International Standing Committee
H. Public Comment
I. Council Discussion and Action

11. Hawaii Archipelago and Pacific Remote Island Areas
A. Moku Pepa
B. Department of Land and Natural Resources/Division of Aquatic Resources Report (Legislation, Enforcement)
C. Green Turtle Management
D. Northwestern Hawaiian Islands Proposed National Marine Sanctuary Update
E. Advisory Group Report and Recommendations
1. AP
2. FIAC
3. NCFAC
4. SSC

F. Public Comment
G. Council Discussion and Action

12. Administrative Matters
A. Council Member and Staff Ethics Training
B. Financial Reports
C. Administrative Reports
D. Fall CCC Report
1. Environmental Justice

E. Proposed Coral Reef Projects
F. Council Family Changes
G. Meetings and Workshops
H. Standing Committee Report
I. Public Comment
J. Council Discussion and Action

13. Other Business
14. Election of Officers

Non-emergency issues not contained in this agenda may come before the Council for discussion and formal Council action during its 189th meeting. However, Council action on regulatory issues will be restricted to those issues specifically listed in this document and any regulatory issue arising after publication of this document that requires emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

These meetings are accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 10, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–24964 Filed 11–15–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB585]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Groundfish Committee via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Tuesday, November 30, 2021, at 9:30 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/7597990804617351436.*

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee will consider the recommendations of the Recreational

Advisory Panel, Groundfish Advisory Panel, and Groundfish Plan Development Team. They willdiscuss draft alternatives and draft impacts analysis and make recommendations to the Groundfish Committee for Framework Adjustment 63 final action. The panel will make recommendations to the Committee, as appropriate, regarding possible 2022 Council priorities. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 10, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–24962 Filed 11–15–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB579]

Endangered and Threatened Species; Take of Anadromous Fish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; Issuance of one Endangered Species Act (ESA) Incidental Take Permit and one ESA Enhancement of Survival Permit; Availability of the Final Environmental Assessment and Finding of No Significant Impact.

SUMMARY: Notice is hereby given that NMFS has issued one Incidental Take Permit and one Enhancement of Survival Permit to Sierra Pacific Land & Timber Company (SPL&T) for the Sierra Pacific Industries Habitat Conservation Plan (HCP) and Safe Harbor Agreement (SHA). The HCP/SHA was submitted pursuant to the Endangered Species Act (ESA) of 1973, as amended. NMFS has also prepared a Final Environmental Assessment (EA) and a Finding of No Significant Impact (FONSI) under the National Environmental Policy Act (NEPA) associated with NMFS' issuance of the Permits for the HCP/SHA. The Permits authorize incidental take of ESA-listed species as set forth in the HCP/SHA for a 50-year period.

DATES: The Incidental Take Permit (No. 24396) and the Enhancement of Survival Permit (No. 24397) were issued to SPL&T on September 29, 2021. Subsequent to issuance, the necessary countersignatures by the applicants were received on October 4, 2021. The expiration date of the permits is October 4, 2071. The issued permits are subject to certain conditions set forth therein.

ADDRESSES: The permits, the Final EA and FONSI, and other related documents available on the NMFS West Coast Region website at: *https://www.fisheries.noaa.gov/action/habitat-conservation-plan-and-safe-harbor-agreement-sierra-pacific-industries-forestland.*

FOR FURTHER INFORMATION CONTACT: Amanda Cranford, Sacramento, CA, at phone number: (916) 930–3706, or via email: *Amanda.Cranford@noaa.gov.*

SUPPLEMENTARY INFORMATION:

ESA-Listed Species Covered in This Notice

Chinook salmon (*Oncorhynchus tshawytscha*), (Evolutionary Significant Unit [ESU]): Central Valley spring-run ESU, and Sacramento River winter-run ESU

Coho salmon (*O. kisutch*), (ESU): Southern Oregon/Northern California Coast ESU

Steelhead (*O. mykiss*), (Distinct Population Segment [DPS]): California Central Valley DPS

Background

SPL&T is the largest private forest landowner in the state of California, with ownership currently encompassing approximately 1.79 million acres of timberland throughout the northern and central portions of the state. Sierra Pacific Industries (SPI) is the authorized representative and manager of SPL&T lands. Rivers and streams on portions of SPL&T lands in the Trinity River and Sacramento River basins provide habitat for anadromous salmonids, including species listed under the ESA. SPI's forestland management activities have the potential to adversely affect fish species and their habitats that are listed, or may be listed, under the ESA. Proposed activities under the permits include those activities necessary to implement the forestland management program, in addition to certain mitigation and conservation measures identified in the HCP/SHA.

Section 10(a)(1)(B) of the ESA authorizes NMFS to issue an Incidental Take Permit to non-Federal parties for the potential incidental taking of endangered and threatened species. The HCP provides an assessment of impacts, measures to monitor, minimize, and mitigate for those impacts, and procedures to account for unforeseen or extraordinary circumstances. Under the HCP, SPI will follow the Z'Berg-Nejedly Forest Practice Act and relevant public resource codes, including the current California Forest Practice Rules (CFPRs) for each year of the permit period. SPI fully complies with the CFPRs, which set prescriptive standards for natural resource protection minimization measures for all activities. The CFPRs set even higher standards for activities in Anadromous Salmonid Protection watersheds. SPI will also implement conservation measures described in the HCP that are designed to protect riparian resources and water quality.

The section 10(a)(1)(B) Incidental Take Permit also covers three species that are not currently listed under the ESA: Central Valley fall/late fall-run Chinook salmon (*O. tshawytscha*) ESU, which is designated as species of concern by NMFS; Upper Klamath/Trinity Rivers Chinook salmon (*O. tshawytscha*) ESU, which is currently petitioned for listing as threatened or endangered under the ESA and endangered under the California Endangered Species Act; and Klamath Mountains Province steelhead (*O. mykiss*) DPS, which has no current regulatory status. The non-listed species identified above do not currently have protective federal regulations against take, and a federal permit is not needed to incidentally take them. However, there may be a change in listing status during the permit term. If any of the above-mentioned non-listed species are listed as threatened or endangered in the future, the section 10(a)(1)(B) Incidental Take Permit would become effective immediately for these species.

The incidental taking identified in the SHA is authorized under a section 10(a)(1)(A) Enhancement of Survival Permit. The SHA addresses potential

impacts resulting from SPI's timber harvest activities on SPL&T lands in the Sacramento and Trinity River basins upstream of currently impassable dams, where NMFS is proposing to reintroduce populations of ESA-listed salmonids. The purpose of the SHA is to provide incentives for non-Federal property owners to voluntarily conduct beneficial management activities that either support or attract ESA-listed species. The beneficial management activities proposed under the SHA will improve habitat within the SHA Plan Area by using SPI's Road Erosion and Sediment Delivery Index (READI) model to identify sources of sediment from road runoff. Road watercourse crossing improvements will be applied, such as new drains and road surfacing, to reduce sediment delivery to the maximum extent practicable. SPI will also support ESA-listed species reintroduction efforts proposed by NMFS, which is expected to contribute towards the recovery of ESA-listed anadromous fish populations in the Sacramento River and Trinity River basins. These actions are expected to provide a net conservation benefit for ESA-listed salmonids.

On June 19, 2020, NMFS published a Notice of Receipt and Notice of Availability in the **Federal Register** (85 FR 37070; June 19, 2020) asking for public comments on the draft HCP/SHA and the associated draft NEPA EA. NMFS received three letters from the public expressing support for the HCP/SHA and the proposed issuance of the permits. No changes were made in response to the comments received, as none were suggested or requested by the public.

Authority

Section 9 of the ESA and Federal regulations prohibit the taking of a species listed as endangered or threatened. The ESA defines ''take'' to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. NMFS may issue permits under limited circumstances to take listed species. Section 10(a)(1)(B) of the ESA and implementing regulations (50 CFR 222.307) provide for authorizing take of listed species, incidental to, and not the purpose of, the carrying out of an otherwise lawful activity.

Enhancement of Survival permits are issued in accordance with Section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 *et seq.*) and regulations governing listed fish and wildlife permits (50 CFR 222.308). NMFS issues permits based on findings that such permits: (1) Are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; and (3) are consistent with the purposes and policy of section 2 of the ESA. The authority to take listed species is subject to conditions set forth in the permits.

Dated: November 10, 2021.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–24927 Filed 11–15–21; 8:45 am]

BILLING CODE 3510–22–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2021–0020]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Consumer Financial Protection (Bureau) is requesting to renew the Office of Management and Budget's (OMB's) approval for an existing information collection titled ''Certification of Vaccination.''

DATES: Written comments are encouraged and must be received on or before January 18, 2022 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: PRA_Comments@cfpb.gov.* Include Docket No. CFPB–2021–0020 in the subject line of the email.
- *Mail/Hand Delivery/Courier:* Comment intake, Bureau of Consumer Financial Protection (Attention: PRA Office), 1700 G Street NW, Washington, DC 20552. Please note that due to circumstances associated with the COVID–19 pandemic, the Bureau discourages the submission of comments by mail, hand delivery, or courier. Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.regulations.gov.* Requests for additional information should be directed to Anthony May, Paperwork Reduction Act Officer, at (202) 435–7278, or email: *CFPB_PRA@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.* Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Certification of Vaccination.

OMB Control Number: 3170–0075.

Type of Review: Extension of a currently approved information collection.

Affected Public: Individuals.

Estimated Number of Respondents: 1,500.

Estimated Total Annual Burden Hours: 125.

Abstract: The Consumer Financial Protection Bureau (CFPB or the Bureau) established safety protocols for both fully vaccinated and unvaccinated people. This information collection (*i.e.,* the Certification of Vaccination form) will ascertain individuals' vaccination statuses to the Bureau to comply with Executive Order 13991 titled ''Protecting the Federal Workforce and Requiring Mask-Wearing.'' In compliance with guidance from the Centers for Disease Control and Prevention (CDC) and the Safer Federal Workforce Task Force, the Bureau is collecting this information from fully vaccinated individuals so that they can comply with Bureau safety guidelines. The Bureau is also collecting this information from partially or unvaccinated individuals so that that other measures can be implemented to enforce Bureau safety guidelines (*e.g.,* wearing masks, physical/social distancing, regular testing, adherence to applicable travel requirements). The Bureau collects these data to promote the safety of Federal buildings, the Federal workforce, and others on site at agency facilities consistent with the COVID–19 Workplace Safety: Agency Model Safety Principles established by the Safer Federal Workforce Task Force and guidance from the CDC and the Occupational Safety and Health Administration. Specifically, Bureau staff will use these data for implementing and enforcing workplace safety protocols.

Request for Comments: Comments are invited on: (a) Whether the collection of

information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Dated: November 10, 2021.

Anthony May,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2021–24974 Filed 11–15–21; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2021–0019]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Consumer Financial Protection (Bureau) is requesting to renew the Office of Management and Budget (OMB) approval for an existing information collection titled ''Generic Information Collection Plan for the Collection of Qualitative Feedback on Bureau Service Delivery.''

DATES: Written comments are encouraged and must be received on or before January 18, 2022 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: PRA_Comments@cfpb.gov.* Include Docket No. CFPB–2021–0019 in the subject line of the email.
- *Mail/Hand Delivery/Courier:* Comment intake, Bureau of Consumer Financial Protection (Attention: PRA Office), 1700 G Street NW, Washington, DC 20552. Please note that due to circumstances associated with the COVID–19 pandemic, the Bureau discourages the submission of comments by mail, hand delivery, or courier. Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.regulations.gov.* Requests for additional information should be directed to Anthony May, Paperwork Reduction Act Officer, at (202) 435–7278, or email: *CFPB_PRA@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.* Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Generic Information Collection for the Collection of Qualitative Feedback on Bureau Service Delivery.

OMB Control Number: 3170–0024.

Type of Review: Extension of a currently approved information collection.

Affected Public: Individuals; Private sector; and State, Local, or Tribal Governments.

Estimated Number of Respondents: 500,000.

Estimated Total Annual Burden Hours: 125,000.

Abstract: This generic information collection plan provides for the collection of qualitative feedback from consumers, financial institutions, and stakeholders on a wide range of services the Bureau provides in an efficient, timely manner, in accordance with the Bureau's commitment to improving service delivery. By qualitative feedback, the Bureau means information that provides useful insights on, for example, comprehension, usability, perceptions, and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. The Bureau expects this feedback to include insights into consumer, financial institution, or stakeholder perceptions, experiences, and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the Bureau and consumers, financial institutions, and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Dated: November 9, 2021.

Anthony May,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2021–24953 Filed 11–15–21; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF EDUCATION

Applications for New Awards; American Indian Vocational Rehabilitation Services

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for Federal fiscal year (FFY) 2022 for American Indian Vocational Rehabilitation Services (AIVRS)—Assistance Listing Number 84.250P—to partner with Indian Tribes in providing eligible American Indians with disabilities with vocational rehabilitation (VR) services. This notice relates to the approved information collection under OMB control number 1820–0018.

DATES:

Applications Available: November 16, 2021.

Deadline for Transmittal of Applications: March 16, 2022.

Pre-Application Webinar Information: The Department will hold a pre-application meeting via webinar for prospective applicants on December 20, 2021, 2:00PM Eastern Time. Details about the pre-application meeting will be available at *https://ncrtm.ed.gov/RSAGrantInfo.aspx.*

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Joy Harris-Summerville, U.S. Department of Education, 400 Maryland Avenue SW, Room 5056E, Potomac Center Plaza, Washington, DC 20202–2800. Telephone: (202) 245–8240. Email: *Joy.Harris@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of this program is to make grants to the governing bodies of Indian tribes located on Federal and State reservations (and consortia of those governing bodies) to provide VR services, including culturally appropriate services, to American Indians with disabilities who reside on or near such reservations, consistent with such eligible individuals' strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice, so that such individuals may prepare for, and engage in, high-quality employment that will increase opportunities for economic self-sufficiency.

Priority: In accordance with 34 CFR 75.105(b)(2)(iv), this priority is from section 121(b)(4) of the Rehabilitation Act of 1973, as amended (Rehabilitation Act) (29 U.S.C. 741(b)(4)).

Competitive Preference Priority: For FY 2022, and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i), we award an additional five points to an application that meets this priority.

This priority is:

Continuation of Previously Funded Tribal Programs.

In making new awards under this program, we give priority to applications for the continuation of programs that have been funded under the AIVRS program.

Program Authority: 29 U.S.C. 741.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in the Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 81, 82, and 84. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 371.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration intends to use approximately $4,369,250 for new awards for this program for FFY 2022. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: $300,000–$550,000.

Estimated Average Size of Award: $546,156.

Estimated Number of Awards: 8.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* Applications may be made only by Indian Tribes (and consortia of those Indian Tribes) located on Federal and State reservations. The definition of ''Indian Tribe'' in section 7(19)(B) of the Rehabilitation Act is ''any Federal or State Indian tribe, band, rancheria, pueblo, colony, or community, including any Alaskan native village or regional village corporation (as defined in or established pursuant to the Alaska Native Claims Settlement Act) and a tribal organization (as defined in section 4(1) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(1)).''

''Reservation'' is defined in 34 CFR 371.6 as ''a Federal or State Indian reservation, public domain Indian allotment, former Indian reservation in Oklahoma, land held by incorporated Native groups, regional corporations and village corporations under the provisions of the Alaska Native Claims Settlement Act; or a defined area of land recognized by a State or the Federal Government where there is a concentration of tribal members and on which the tribal government is providing structured activities and services.''

The applicant for an AIVRS grant must be—

(1) The governing body of an Indian Tribe, either on behalf of the Indian Tribe or on behalf of a consortium of Indian Tribes; or

(2) A Tribal organization that is a separate legal organization from an Indian Tribe.

To receive an AIVRS grant, a Tribal organization that is not a governing body of an Indian Tribe must—

(1) Have as one of its functions the vocational rehabilitation of American Indians with disabilities; and

(2) Have the approval of the Tribe to be served by such organization.

If a grant is made to the governing body of an Indian Tribe, either on its own behalf or on behalf of a consortium, or to a Tribal organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the making of such a grant.

2. a. *Cost Sharing or Matching:* Cost sharing is required by section 121(a) of the Rehabilitation Act and 34 CFR 371.40 at 10 percent of the total cost of the project.

b. *Indirect Cost Rate Information:* This program uses an unrestricted indirect cost rate. Applicants for this program are the governing bodies of Indian Tribes (or consortia of governing bodies) and have negotiated indirect cost rate agreements with a cognizant agency if indirect costs will be charged to the grant. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All

administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application. While subgrants are not permitted, under 34 CFR 371.42(a), grantees are permitted to provide the VR services by contract or otherwise enter into an agreement with a designated State unit (DSU), a community rehabilitation program, or another agency to assist in the implementation of the Tribal VR program, as long as such contract or agreement is identified in the application.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application.

2. *Intergovernmental Review:* This competition is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

3. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210, have a maximum score of 100 points, and are as follows:

(a) *Need for Project and Significance* (10 Points): The Secretary considers the need for and significance of the proposed project. In determining the need for and significance of the proposed project, the Secretary considers the following factors:

(1) The magnitude of the need for the services to be provided or the activities to be carried out by the proposed project.

(2) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.

(3) The potential contribution of the proposed project to increased knowledge or understanding of rehabilitation problems, issues, or effective strategies.

(4) The extent to which the proposed project is likely to build local capacity to provide, improve, or expand services that address the needs of the target population.

(b) *Quality of the Project Design* (20 Points):

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(2) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs.

(3) The extent to which the proposed project will establish linkages with other appropriate agencies and organizations providing services to the target population.

(c) *Quality of Project Services* (20 Points):

The Secretary considers the quality of the services to be provided by the proposed project. In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

In addition, the Secretary considers the following factors:

(1) The extent to which the services to be provided by the proposed project are appropriate to the needs of the intended recipients or beneficiaries of those services.

(2) The likely impact of the services to be provided by the proposed project on the intended recipients of those services.

(3) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services.

(d) *Quality of Project Personnel* (15 Points):

The Secretary considers the quality of the personnel who will carry out the proposed project. In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

In addition, the Secretary considers the qualifications, including relevant training and experience, of key project personnel.

(e) *Adequacy of Resources* (10 Points):

The Secretary considers the adequacy of resources for the proposed project. In determining the adequacy of resources for the proposed project, the Secretary considers the following factors:

(1) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization.

(2) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

(3) The extent to which the costs are reasonable in relation to the number of persons to be served and to the anticipated results and benefits.

(f) *Quality of the Management Plan* (15 Points):

The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(2) The adequacy of procedures for ensuring feedback and continuous improvement in the operation of the proposed project.

(3) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(g) *Quality of the Project Evaluation* (10 Points):

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

(1) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(2) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce

quantitative and qualitative data to the extent possible.

(3) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

Applicants for the AIVRS program must provide evidence regarding the following special application requirements in 34 CFR 371.21(a)–(k). The application package includes a Special Application Requirements form in Section D that must be completed. An application is not complete without the Special Application Requirements form, provided in the application package, and will not be considered for review without that completed form. These requirements are:

(a) Effort will be made to provide a broad scope of vocational rehabilitation services in a manner and at a level of quality at least comparable to those services provided by the designated State unit.

(b) All decisions affecting eligibility for vocational rehabilitation services, the nature and scope of available vocational rehabilitation services and the provision of such services will be made by a representative of the Tribal vocational rehabilitation program funded through this grant and such decisions will not be delegated to another agency or individual.

(c) Priority in the delivery of vocational rehabilitation services will be given to those American Indians with disabilities who are the most significantly disabled.

(d) An order of selection of individuals with disabilities to be served under the program will be specified if services cannot be provided to all eligible American Indians with disabilities who apply.

(e) All vocational rehabilitation services will be provided according to an individualized plan for employment which has been developed jointly by the representative of the Tribal vocational rehabilitation program and each American Indian with disabilities being served.

(f) American Indians with disabilities living on or near Federal or State reservations where Tribal vocational rehabilitation service programs are being carried out under this part will have an opportunity to participate in matters of general policy development and implementation affecting vocational rehabilitation service delivery by the Tribal vocational rehabilitation program.

(g) Cooperative working arrangements will be developed with the DSU, or DSUs, as appropriate, which are providing vocational rehabilitation services to other individuals with disabilities who reside in the State or States being served.

(h) Any comparable services and benefits available to American Indians with disabilities under any other program, which might meet in whole or in part the cost of any vocational rehabilitation service, will be fully considered in the provision of vocational rehabilitation services.

(i) Any American Indian with disabilities who is an applicant or recipient of services, and who is dissatisfied with a determination made by a representative of the Tribal vocational rehabilitation program and files a request for a review, will be afforded a review under procedures developed by the grantee comparable to those under the provisions of section 102(c)(1)–(5) and (7) of the Rehabilitation Act.

(j) The Tribal vocational rehabilitation program funded under this part must assure that any facility used in connection with the delivery of vocational rehabilitation services meets facility and program accessibility requirements consistent with the requirements, as applicable, of the Architectural Barriers Act of 1968, the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act, and the regulations implementing these laws.

(k) The Tribal vocational rehabilitation program funded under this part must ensure that providers of vocational rehabilitation services are able to communicate in the native language of, or by using an appropriate mode of communication with, applicants and eligible individuals who have limited English proficiency, unless it is clearly not feasible to do so.

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with:

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

5. *Performance Measures:* For the purposes of the Government Performance and Results Act of 1993 (GPRA), and reporting under 34 CFR 75.110, the Department has established four performance measures for the AIVRS program. The measures are:

(a) Of all those exiting the program, the percentage of individuals who leave the program with an employment outcome after receiving services under an individualized plan for employment (IPE).

(b)(1) The percentage of individuals who leave the program with an employment outcome after receiving services under an IPE.

(2) The percentage of individuals who leave the program without an employment outcome after receiving services under an IPE.

(3) The percentage of individuals who have not left the program and are continuing to receive services under an IPE.

(c) The percentage of projects that demonstrate an average annual cost per employment outcome of no more than $35,000.

(d) The percentage of projects that demonstrate an average annual cost of services per participant of no more than $10,000.

Each grantee must annually report the data needed to measure its performance on the GPRA measures through the Annual Performance Reporting Form (APR Form) for the AIVRS program.

Note: For purposes of this section, the term ''employment outcome'' means, with respect to an individual, (a) entering or retaining full-time or, if appropriate, part-time competitive employment in the integrated labor market; (b) satisfying the vocational outcome of supported employment; or (c) satisfying any other vocational outcome the Secretary of Education may determine to be appropriate (including satisfying the vocational outcome of customized employment, self-employment, telecommuting, or business ownership). (Section 7(11) of the Rehabilitation Act (29 U.S.C. 705(11)).

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit

your search to documents published by the Department.

Katherine Neas,

Acting Assistant Secretary, Office of Special Education and Rehabilitative Services.

[FR Doc. 2021–24887 Filed 11–15–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[Case Number 2021–004; EERE–2021–BT–WAV–0009]

Energy Conservation Program: Notification of Petition for Waiver of GE Appliances, a Haier Company, From the Department of Energy Miscellaneous Refrigeration Products Test Procedure

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notification of petition for waiver; request for comments.

SUMMARY: This notification announces receipt of and publishes a petition for waiver from GE Appliances, a Haier Company, which seeks a waiver for a specified miscellaneous refrigeration product basic model from the U.S. Department of Energy (''DOE'') test procedure used for determining the energy consumption of these products. DOE solicits comments, data, and information concerning the petition and its suggested alternate test procedure so as to inform DOE's final decision on the waiver request.

DATES: Written comments and information are requested and will be accepted on or before December 16, 2021.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov.* Alternatively, interested persons may submit comments, identified by docket number EERE–2021–BT–WAV–0009, by any of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.

2. *Email:* to *AS_Waiver_Requests@ee.doe.gov.* Include docket number EERE–2021–BT–WAV–0009 in the subject line of the message.

No telefacsimiles (''faxes'') will be accepted. For detailed instructions on submitting comments and additional information on this process, see the **SUPPLEMENTARY INFORMATION** section of this document.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing coronavirus disease 2019 (''COVID–19'') pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this change poses an undue hardship, please contact Appliance Standards Program staff at (202) 586–1445 to discuss the need for alternative arrangements. Once the COVID–19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

Docket: The docket, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at *www.regulations.gov/docket/EERE-2021-BT-WAV-0009.* The docket web page contains instruction on how to access all documents, including public comments, in the docket. See the **SUPPLEMENTARY INFORMATION** section for information on how to submit comments through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Ms. Julia Hegarty, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Email: *AS_Waiver_Request@ee.doe.gov.*

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–33, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0103. Telephone: (202) 586–8145. Email: *Michael.Kido@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE is publishing GEA's petition for waiver in its entirety, pursuant to 10 CFR 430.27(b)(1)(iv).[1] DOE invites all interested parties to submit in writing by December 16, 2021, comments and information on all aspects of the petition, including the alternate test procedure. Pursuant to 10 CFR 430.27(d), any person submitting written comments to DOE must also send a copy of such comments to the petitioner. The contact information for the petitioner is:

John T. Schlafer, GE Appliances, A Haier Company, Appliance Park—AP2–225, Louisville, KY 40225. Email: *john.schlafer@geappliances.com.*

Submitting comments via www.regulations.gov. The *www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. If this instruction is followed, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (''CBI'')). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

[1] The petition did not identify any of the information contained therein as confidential business information.

Submitting comments via email. Comments and documents submitted via email also will be posted to *www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. Faxes will not be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: One copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. Submit these documents via email. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

I. Background and Authority

The Energy Policy and Conservation Act, as amended (''EPCA''),[2] authorizes the U.S. Department of Energy (''DOE'') to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part B [3] of EPCA, Public Law 94–163, as amended (42 U.S.C. 6291–6309, as codified), established the Energy Conservation Program for Consumer Products Other Than Automobiles, which, in addition to identifying particular types of consumer products and commercial equipment as covered under the statute, permits the Secretary of Energy to classify additional types of consumer products as covered products. (42 U.S.C. 6292(a)(20)) DOE added miscellaneous refrigeration products (''MREFs'') as covered products through a final determination of coverage published in the **Federal Register** on July 18, 2016 (the ''July 2016 Final Rule''). 81 FR 46768. *Id.*

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

The Federal testing requirements consist of test procedures that manufacturers of covered products must use as the basis for: (1) Certifying to DOE that their products comply with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6295(s)), and (2) making representations about the efficiency of that product (42 U.S.C. 6293(c)). Similarly, DOE must use these test procedures to determine whether the covered product complies with relevant standards promulgated under EPCA. (42 U.S.C. 6295(s))

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE is required to follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect the energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

MREFs are consumer refrigeration products other than refrigerators, refrigerator-freezers, or freezers. These products include coolers and combination cooler refrigeration products. 10 CFR 430.2. A ''cooler'' is a cabinet, used with one or more doors, that has a source of refrigeration capable of operating on single-phase, alternating current and is capable of maintaining compartment temperatures either: (1) No lower than 39 °F (3.9 °C); or (2) in a range that extends no lower than 37 °F (2.8 °C) but at least as high as 60 °F (15.6 °C) as determined according to the applicable DOE test procedure. The test procedure for MREFs is contained in the Code of Federal Regulations (''CFR'') at 10 CFR part 430, appendix A to subpart B of part 430—Uniform Test Method for Measuring the Energy Consumption of Refrigerators, Refrigerator-Freezers, and Miscellaneous Refrigeration Products (''Appendix A'').

Under 10 CFR 430.27, any interested person may submit a petition for waiver from DOE's test procedure requirements. DOE will grant a waiver from the test procedure requirements if DOE determines either that the basic model for which the waiver was requested contains a design characteristic that prevents testing of the basic model according to the prescribed test procedures, or that the prescribed test procedures evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 430.27(f)(2). A petitioner must include in its petition any alternate test procedures known to the petitioner to evaluate the performance of the product type in a manner representative of the energy consumption characteristics of the basic model. 10 CFR 430.27(b)(1)(iii). DOE may grant the waiver subject to conditions, including adherence to alternate test procedures. 10 CFR 430.27(f)(2).

As soon as practicable after the granting of any waiver, DOE will publish in the **Federal Register** a notice of proposed rulemaking to amend its regulations so as to eliminate any need for the continuation of such waiver. 10 CFR 430.27(l). As soon thereafter as practicable, DOE will publish in the **Federal Register** a final rule to that effect. *Id.*

The waiver process also provides that DOE may grant an interim waiver if it

[2] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020).

[3] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated as Part A.

appears likely that the underlying petition for waiver will be granted and/or if DOE determines that it would be desirable for public policy reasons to grant immediate relief pending a determination on the underlying petition for waiver. 10 CFR 430.27(e)(2). Within one year of issuance of an interim waiver, DOE will either: (i) Publish in the **Federal Register** a determination on the petition for waiver; or (ii) publish in the **Federal Register** a new or amended test procedure that addresses the issues presented in the waiver. 10 CFR 430.27(h)(2).

If DOE ultimately denies the petition for waiver, DOE will provide a period of 180 days before the manufacturer is required to use the DOE test procedure to make representations of energy efficiency. 10 CFR 430.27(i). When DOE amends the test procedure to address the issues presented in a waiver, the waiver will automatically terminate on the date on which use of that test procedure is required to demonstrate compliance. 10 CFR 430.27(h)(3).

II. GEA's April 2021 Petition for Waiver and Interim Waiver

On April 9, 2021, DOE received from GE Appliances, a Haier Company (''GEA'') a petition (dated April 8, 2021) for waiver and interim waiver from the test procedure for MREFs set forth at appendix A to subpart B of 10 CFR part 430. (GEA, No. 1 at p. 1) [4] Pursuant to 10 CFR 430.27(e)(i), DOE posted the petition on the DOE website at: *www.regulations.gov/document/EERE-2021-BT-WAV-0009-0001*.[5]

The specific basic model subject to the petition was ''S–IHG–R'', which GEA described as an ''In-Home Grower''—a product with lighting, temperature, humidity, and nutrient water control that allows the user to grow plants within their home year-round. GEA stated that the average compartment temperatures of the In-Home Grower exceed the 55 °F standardized temperature required for testing under the existing DOE test procedure (see section 3.2 of appendix A) and, therefore, the product cannot be tested using the existing test procedure. GEA also described characteristics of this basic model that GEA stated would prevent the use of certain test setup, stabilization, temperature control, and energy use determination requirements in appendix A. (GEA, No. 1 at pp. 3–4)

In its April 8, 2021 petition, GEA submitted to DOE an alternate test procedure to determine the energy consumption of its In-Home Grower. (GEA, No. 1 at p. 6) GEA stated that its alternate test procedure would allow for the measurement of the energy use of this product where the requirements of the current DOE test procedure cannot be met. DOE received a follow-up correspondence from GEA on April 26, 2021, which provided a revised alternate test procedure.[6] DOE reviewed the alternate test procedure included in the April 26, 2021 correspondence as the requested alternate test approach when making the initial determination on the petition for waiver and interim waiver. GEA also provided additional correspondence on June 2, 2021, in which it clarified certain aspects of the proposed alternate test procedure included in the April 26, 2021 submission.[7] In the April 26, 2021, correspondence, GEA requested an alternate test approach in which two tests would be conducted for the subject basic model: one with the model operating as ''normal,'' and the other with the refrigeration system disabled to allow for identifying the energy contribution of the cooling system. GEA stated that the main purpose of the cooling system is to counteract the heat generated from the internal lighting, and that the requested alternate test procedure would be used to determine the energy consumption of the cooling system only. (GEA, No. 2 at p. 4)

On July 7, 2021, DOE published a notification of petition for waiver and denial of an interim waiver for the alternative test approach described by GEA in its April 26, 2021 correspondence. 86 FR 35766. In that notification, DOE acknowledged that, based upon GEA's petition, absent an interim waiver, GEA's In-Home Grower cannot be tested and rated for energy consumption according to the MREF test procedure on a basis representative of its true energy consumption characteristics. *Id.* at 86 FR 35768. However, DOE tentatively determined that GEA's proposed alternative test procedure would not result in a measurement of the energy use of the basic model that is representative of an average use cycle or period of use, and therefore the petition for waiver was unlikely to be granted as submitted. *Id.* Specifically, DOE determined that the requested test approach to isolate the refrigeration system energy consumption would not provide a representative measurement of energy use for the basic model during an average use cycle or period of use. 86 FR 35766, 35770. DOE requested comment on all aspects of the petition, including the suggested alternate test procedure and calculation methodology. *Id.*

III. GEA's September 2021 Petition for Waiver

On September 17, 2021, GEA submitted to DOE a new petition for waiver (''September 2021 petition for waiver'') for the same basic model with a revised alternate test approach.[8] The following two sections discuss specific aspects of GEA's September 2021 petition for waiver.

A. Requirements Sought To Be Waived

GEA requested to waive the current test procedure, calculations, and accompanying conditions for testing coolers as specified in section 6.2.2 of appendix A. GEA asserted that the In-Home Grower is fundamentally different from all other known miscellaneous refrigeration products. The primary assertion of the petition is that the basic model for which the waiver was requested contains design characteristics that prevent testing of the basic model according to the prescribed DOE MREF test procedure. GEA states that the In-Home Grower, when tested at its coldest setting in a 90 °F ambient temperature, cannot achieve the 55 °F standardized temperature required for the DOE MREF test procedure (see section 3.2 of appendix A). GEA stated that its testing in a 90 °F ambient condition resulted in compartment temperatures of 79.90 °F and 79.97 °F.

The DOE test procedure at appendix A simulates typical room conditions (72 °F) with door openings, by testing at 90 °F without door openings. 10 CFR 430.23(ff)(7). The test procedure directly measures the energy consumed during steady-state operation and defrosts, if applicable. Additionally, the DOE test procedure incorporates usage adjustment factors to account for differences in these user-related thermal loads for different types of consumer refrigeration products (*i.e.,* MREFs are typically used less frequently than a primary refrigerator-freezer in a household and thus have an adjustment

[4] A notation in this form provides a reference for information that is in the docket for this test procedure waiver (Docket No. EERE–2021–BT–WAV–0009) (available at *www.regulations.gov/docket/EERE-2021-BT-WAV-0009*). This notation indicates that the statement preceding the reference is document number 1 in the docket and appears at page 1 of that document.

[5] The petition did not identify any of the information contained therein as confidential business information.

[6] This document can be found in the docket for this test procedure waiver under Document No. 002.

[7] This document can be found in the docket for this test procedure waiver under Document No. 003.

[8] This document can be found in the docket for this test procedure waiver under Document No. 006.

factor of 0.55). See section 5.2.1.1 of appendix A.

GEA states that there is no need to elevate the ambient temperature for the test to account for door openings and loads because the In-Home Grower has a very low number of door openings and, after the initial loading with plants, will typically not have additional loads introduced. GEA seeks to waive the requirement for testing the In-Home Grower at a 90 °F ambient condition. See section 2.1.1 of appendix A. GEA instead requests to test the In-Home Grower in a 72 °F ambient condition, which it asserts better represents typical use of the product. GEA further stated that testing at a 72 °F ambient with the product temperature set to 60 °F (the minimum temperature set point) yields compartment temperatures between 59.15 and 61.41 °F. GEA also seeks to waive the requirement in section 6.2.2 of appendix A that performance be calculated at a standardized compartment temperature of 55 °F, since the In-home Grower is not capable of maintaining the 55 °F standardized compartment temperature specified in appendix A. Instead, GEA requests that the model be tested in the 72 °F ambient condition using default settings.

Additionally, GEA seeks to waive the existing DOE test procedure requirement to measure the internal compartment temperatures of the unit under test. See section 5.1 of appendix A. GEA claims that the rotation of the compartments significantly increases the test burden of temperature measurements, as the thermocouple wires would require a customized testing setup to avoid tangling of the wires and movement of the temperature masses. Under GEA's requested approach, compartment temperature measurements would not be necessary because no interpolation would be made to reflect performance at the standardized 55 °F compartment temperature. (GEA, No. 6 at p. 4)

GEA also seeks to waive the stabilization and test period requirements specified in sections 2.9 and 4 of appendix A, respectively. Specifically, GEA requests an 8-hour stabilization period (the duration of each rotation) and 24-hour test period (the duration of one full rotation) based on the rotation of the internal compartments, rather than based on compressor cycling as specified in appendix A. (GEA, No. 6 at p. 4)

B. Requested Alternate Test Procedure

GEA seeks to use an alternate test procedure to test and rate a specific MREF basic model. GEA's requested alternate test procedure addresses the test procedure requirements to be waived as discussed in the previous section of this document. GEA's requested approach also includes additional test instructions regarding setup and settings instructions.

Because the In-Home Grower supplies water and nutrients to plants during normal operation, GEA's suggested alternate test procedure provides instructions for filling nutrient tanks with ambient-temperature water prior to the start of the test.

The proposed alternate test approach also provides instructions for product settings, as the suggested test procedure would not be based on the product maintaining compartment temperature to the 55 °F standardized compartment temperature specified in appendix A. Specifically, GEA requests that the In-Home Grower be controlled via use of an application on a connected device and that the product be operated using default settings.

In summary, GEA's suggested alternate test procedure would measure the daily energy consumption of the basic model by providing:

(1) Directions for filling the nutrient water tanks with water at ambient temperature;

(2) A specific stabilization period of 8 hours (in place of the requirements of section 2.9 of appendix A);

(3) A specific test period of 24 hours (in place of the test period described in section 4.1 of appendix A);

(4) An ambient test condition of 72 °F (in place of the requirement in section 2.1.1 of appendix A);

(5) That no compartment temperature measurements be taken during the test (in place of the requirements in section 5.1 of appendix A); and

(6) That the product be controlled using an application from a connected device and operated using default settings. (GEA, No. 6 at p. 6)

IV. DOE Response and Request for Comments

As the September 17, 2021 petition is for the same basic model that is the subject of the petition addressed in the July 7, 2021 **Federal Register** notification, DOE is treating the September 17, 2021 petition as an amendment to the prior petition. DOE reiterates its determination from the July 7, 2021 notification that based on GEA's description of the In-Home Grower, the basic model meets the definition of a cooler in 10 CFR 430.2 for the following reasons:

1. The product consists of a cabinet used with one or more glass doors, as specified by GEA; and

2. The product maintains compartment temperatures no lower than 39 °F, as determined when tested in a 90 °F ambient temperature, as GEA specified that the compartment temperatures measured 79.90 °F and 79.97 °F under these conditions at the minimum temperature setting. 86 FR 35766, 35768.

The definition for cooler at 10 CFR 430.2 does not reference a specific design intent (such as storage of food or beverages) and does not require that the product be capable of maintaining a compartment temperature of 55 °F when tested in a 90 °F ambient temperature. *Id.* While DOE maintains its determination that the subject basic model meets the definition of a cooler in 10 CFR 430.2, DOE acknowledges the significant differences between this basic model and typical MREFs (and more specifically, coolers).[9] Based on the product design and operation details provided by GEA, DOE has tentatively determined that the basic model under consideration is substantially different than the coolers considered in the analysis used to develop the current cooler standards. DOE considered products for which the refrigeration systems were the main source of energy consumption, and in these products the primary purpose of the refrigeration system is to remove heat that enters the cooler compartment from the outside (*i.e.,* through the walls of the cabinet) in order to maintain the compartment at a temperature lower than the ambient temperature (see chapter 3 of the technical support document to the 2016 direct final rule, document number EERE–2011–BT–STD–0043–0118 found online at *www.regulations.gov*). However, the GEA basic model under question includes an array of lights that are used to facilitate plant growth, but which generate heat, such that the primary purpose of the refrigeration system is to remove heat that is generated internally within the compartment in order to maintain the compartment at approximately the same temperature as the ambient temperature. Based on this difference in function from the other cooler products addressed by DOE's regulations, the

[9] GEA stated in its September 17, 2021, petition for waiver that the subject basic model is fundamentally different from all other known MREFs. Specifically, GEA stated that: (1) The product has a fundamentally different purpose than other MREFs, which are for cooling and storing beverages and food; (2) the primary purpose of the refrigeration system in the product is humidity control; (3) because the product operates at or near ambient temperature, the product is uninsulated, unlike all other known MREFs, which are insulated; and (4) the product contains grow lighting, which both consumes energy and adds heat to the product.

design changes that would improve the efficiency of the subject basic model (*e.g.,* reducing lighting energy use, improving heat transfer through the cabinet walls to allow heat to be more easily transferred out of the cabinet) are significantly different than those considered for coolers during the 2016 rulemaking analysis (*e.g.,* increasing refrigeration system efficiency, improving cabinet insulation to reduce heat transfer through the cabinet walls). Therefore, DOE has tentatively determined that the current cooler energy conservation standards are not applicable to the subject basic model.

This approach is not dissimilar from prior actions taken by DOE to address products or equipment that had not been contemplated under the regulatory framework set out by DOE. For example, in the case of commercial refrigeration equipment, DOE has previously indicated that salad bars, buffet tables, and other refrigerated holding and serving equipment meet the definition of commercial refrigeration equipment. But these equipment operate in a unique manner compared to the other commercial refrigeration equipment that DOE considered when establishing its test procedures and standards. Nevertheless, DOE has determined that salad bars, buffet tables, and other refrigerated holding and serving equipment are covered as commercial refrigeration equipment, but that the current energy conservation standards do not apply to them. 79 FR 22277, 22281 (April 21, 2014).

DOE's 2009 beverage vending machines (''BVM'') energy conservation standards rulemaking and the 2007 distribution transformer energy conservation standards rulemaking are also examples of prior instances where DOE determined that covered products or equipment would not be subject to standards due to their unique design or operation. 81 FR 44914, 44920 (Aug. 31, 2009); 72 FR 58190, 58197 (Oct. 12, 2007).

When DOE initially considered energy conservation standards for BVMs, DOE did not consider combination vending machines as a separate equipment class, but instead considered that equipment with all other Class A and Class B BVMs. DOE later recognized that combination vending machines offered a distinct utility (*i.e.,* storage and vending of refrigerated and unrefrigerated merchandise) and concluded that those machines were a separate class of BVMs. DOE decided to not set standards for the equipment class at that time and reserved standards for combination vending machines (indicating that the Class A and Class B BVM standards were not applicable to combination vending machines) and modified the definition of Class A and Class B BVMs to accommodate a definition for combination vending machines. 74 FR 44914, 44920 (Aug. 31, 2009).

Similarly, in the 2007 energy conservation standards rulemaking for distribution transformers, DOE clarified that although underground mining distribution transformers are within the scope of coverage, it recognized that mining transformers were subject to unique and extreme dimensional constraints that impacted their efficiency and performance capabilities and did not establish energy conservation standards for underground mining transformers. In the final rule, DOE established a separate equipment class for mining transformers with the intent to develop the analysis required to establish an appropriate energy conservation standard in the future. 72 FR 58190, 58197 (Oct. 12, 2007). DOE later reached a similar conclusion in 2013 when it decided again not to establish standards for mining distribution transformers. 78 FR 23336, 23353–23354 (Apr. 18, 2013).

Accordingly, in light of these examples, DOE's tentative views with respect to the applicability of standards to the products at issue are consistent with its past approach in addressing novel products and equipment.

DOE understands, based upon GEA's petition, that absent a waiver, GEA's In-Home Grower cannot be tested and rated for energy consumption according to the MREF test procedure on a basis representative of its true energy consumption characteristics.

DOE has reprinted the September 17, 2021 petition for waiver, including the suggested alternate test procedure, at the end of this notification. DOE may consider including this alternate procedure, or a modified version of this alternate procedure, in a subsequent Decision and Order. DOE solicits comments from interested parties on all aspects of the petition, including the suggested alternate test procedure.

Signing Authority

This document of the Department of Energy was signed on November 9, 2021, by Kathleen B. Hogan, Acting Under Secretary for Science and Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 9, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

John Schlafer
Senior Counsel
Appliance Park—AP2
Louisville, KY 40225
T: (502) 452–7603
john.schlafer@geappliances.com

September 17, 2021

Via Email (*AS_Waiver_Requests@ee.doe.gov*)

Ms. Lucy deButts
U.S. Department of Energy
Office of Energy Efficiency and Renewable Energy
Building Technologies Office
1000 Independence Avenue SW
Mailstop EE–5B
Washington, DC 20585–0121

Re: Petition for Waiver Regarding Test Procedures for Measuring the Energy Consumption of an In-Home Grower Product

Dear Ms. deButts: GE Appliances, a Haier company (GEA) respectfully submits this Petition for Waiver requesting an alternate test procedure from the Department of Energy's (DOE) test procedure for Miscellaneous Refrigeration Products in 10 CFR 430 Subpart B, Appendix A. GEA's request is for a new product that allows users to grow plants within their home the entire year, known as an In-Home Grower. The product is designed to be used in an indoor, temperature-controlled environment with room temperatures from 60 °F to 80 °F. The product provides the lighting, temperature and humidity control, and nutrient water to grow an array of plants. As detailed below, there are numerous reasons that the existing DOE miscellaneous refrigeration products test procedures is not appropriate or impossible to use for the In-Home Grower.

1. About GE Appliances

GEA is a leading US manufacturer of home appliances. GEA offers a full suite of major appliances across seven brands as well as portable appliances. GEA has been a participant in and contributor to the DOE's home appliance energy conservation program since its founding more than 40 years ago. Indeed, GEA

supports the goal of the appliance efficiency program: Maximizing energy savings improvements that offer consumers real economic benefits and that do not diminish product performance. GEA devotes substantial resources to the development of new technologies to increase energy efficiency where they are feasible and engineering products to meet the demanding DOE energy efficiency requirements. GEA manufactures a substantial portion of its refrigerator products at its manufacturing facilities in Louisville, KY, Decatur, AL, and Selmer, TN. The products covered by this waiver request will be manufactured in the United States.

2. Basic Models for Which a Waiver Is Requested

There is no existing Product Class for the In-Home Grower. The Basic Model is S–IHG–R. The basic model will be distributed in commerce under the brand name ''Profile''.

The In-Home Grower allows the user to grow plants within their home year-round. The product provides the lighting, temperature and humidity control and nutrient water needed to grow an array of plants. The product is designed to be in a controlled environment with room temperature from 60 to 80 °F.

The product has a circular grow tower that is in the center of the product. The tower is divided into three equal-sized vertical sections, each comprising ⅓rd of a circular cross section (see Figure 1 below).[10]

[Figure]

Figure 1. Top View of In-Home Grower.

On each of the three sides of the tower are gardens. The three sides of the tower meet up with the curved interior walls of the product cabinet to create three chambers within the product. The tower rotates every eight hours. Each time the tower rotates, a section of the tower enters a new chamber. The front chamber is called the display chamber. This is the side of the garden the owner will see through the front glass doors. In the display chamber, there is no grow lighting. The back right and back left chambers are individually controlled for grow lighting, temperature, and humidity.

The product is primarily controlled by a smart-phone application and connection to the app is obtained through WiFi networking capabilities built into the product.

The grow lighting in the product is LED lighting. The lighting systems uses lamps with a variety of color spectrums. The selection and layout of these lamps is designed to optimize plant growth while minimizing energy consumption.

The product utilizes a vapor-compression cooling system that is primarily intended to control humidity in the product, but which also removes excess heat generated by the grow-lighting system in the rear two chambers.

3. Design Characteristic Constituting Grounds for the Petition

There are multiple reasons why the existing MREF test procedure at 10 CFR 430 Subpart B, Appendix A is either impossible to use or inappropriate to use for the In-Home Grower.

a. Even at the product's coldest setting, the internal compartment temperature does not reach the reference temperature of 55 °F for a miscellaneous refrigeration product when it is run in a 90 °F ambient. Per Table 1 in 10 CFR 430 Subpart B, Appendix A, Section 3.2.1.3, when this condition occurs, ''No Energy Use Rating can be established under the existing test procedure''. Therefore, interpolation to 55 °F is not possible, and the existing DOE interpolation method cannot be used to establish a test result.

b. There is no need to test at an elevated ambient temperature to account for door openings and loading as is the case with the current DOE miscellaneous refrigeration products test procedure. This is true for the following reasons.

i. The In-Home Grower is designed to operate with an internal temperature between 60 °F and 80 °F.

ii. Once loaded with plants, there are a minimal amount of door openings as the product is intended to grow the plants until they are grown and ready for use.

iii. Since the internal temperatures are closer to the ambient temperature, any door openings that did occur would only result in minimal heat addition to the interior.

c. The product has rotating compartments which makes taking internal temperature measurements burdensome if not impossible. Thermocouple wires for refrigeration tests run from inside the unit being tested to a panel box affixed to a wall. The internal compartments of the In-Home Grower rotate during operation. Unique fixtures and test setup would be required to avoid tangling of the wires, movement of the thermocouples, or pulling the wires out of the panel box.

d. The test procedure lacks appropriate setup provisions for this remotely controlled product that requires initial cycle selection and activation.

e. The product is fundamentally different from all other known miscellaneous refrigeration products. These differences include, but are not limited to, the following.

i. The product has a fundamentally different purpose than other miscellaneous refrigeration products, which are for cooling and storing beverages and food.

ii. The primary purpose of the refrigeration system in the product is humidity control.

iii. Because the product operates at or near ambient temperature, the product is uninsulated. This is unlike all other known miscellaneous refrigeration products, which are insulated.

iv. The product contains grow lighting, which both consumes energy and adds heat to the product.

4. Requirements Sought To Be Waived

GEA seeks to replace the current test procedure in Appendix A for Coolers, section 6.2.2, with the accompanying test conditions specified in Exhibit A, attached, for the In-Home Grower.

Instead of a 90 °F ambient, GEA has specified a 72 °F ± 1.0 °F ambient for the testing. This is representative of usage as the product is designed to be placed in an indoor, conditioned space with an ambient between 60 and 80 °F. Also, as stated above, there is no need to elevate the ambient for the test to account for door openings and loads as the product has a very low number of door openings and, after the initial loading with plants, will typically not have additional loads introduced.

The proposed test procedure does not have internal temperature measurements. Based on internal testing in a 90 °F environment, the internal temperatures of the two controlled compartments, at its coldest setting were 79.90 °F and 79.97 °F, well above the 55 °F reference temperature of the DOE MREF test procedure. Also, the rotation of the compartments significantly increases the test burden of temperature measurements as the thermocouple wires would require a setup to avoid tangling of the wires and movement of the temperature masses.

This product has no defrosting capabilities and can be tested similarly to a non-automatic defrost refrigerator. In order to capture a complete cycling of the growing chambers, GEA is proposing a test that has an 8-hour

[10] Product images provided with petition may be found at Docket No. EERE–2021–BT–WAV–0009 at *www.regulations.gov/docket/EERE-2021-BT-WAV-0009.*

stabilization period followed by a 24-hour test period. The growing chambers rotate 120° every 8 hours. This comprises one rotation for stability and three rotations for the test period.

5. Manufacturers of All Other Basic Models With Similar Design Characteristics

To GEA's knowledge, there are no products of this type in the marketplace.

6. Notice to Other Manufacturers

Pursuant to 10 CFR 430.27(c)(2), upon publication of this Petition for Waiver, GEA will notify in writing all known manufacturers of domestically marketed basic models of the same product class (as specified in 10 CFR 430.32) and of other product classes known to the petitioner to use the technology or have the characteristic at issue in the waiver. The notice will include a statement that DOE has published the Petition for Waiver in the **Federal Register** and the date the Petition for Waiver was published. The notice will also include a statement that DOE will receive and consider timely written comments on the petition for waiver. Within five working days of publication of this Petition for Waiver, GEA will file with DOE a statement certifying the names and addresses of each person to whom a notice of the petition for waiver was sent.

7. Conclusion

GEA respectfully requests that DOE grant this Petition for Waiver from the current test procedure for the specified basic models.

Very truly yours,
/s/
John T. Schlafer

Attachments:
Exhibit A—Alternate Test Procedure

Exhibit A—Alternate Test Procedure for In-Home Grower

Energy Consumption is Determined by the Formula:
E = EP * 1440/T

Where:

- E is the test cycle energy (kWh/day)
- 1440 = number of minutes in a day
- EP is the energy expended during three full rotations of the growing chambers (kWh)
- T is the length of time for EP (minutes)

Water in Tanks:

Fill the nutrient and supply tanks with water (72.0 ± 5.0 °F) prior to start of the stabilization period.

Stabilization:

The test shall start after a minimum 8-hour stabilization run for each temperature control setting. This constitutes one rotation of the growing chambers.

Ambient Temperature:

Measure and record the ambient temperature at points located 3 feet (91.5 cm) above the floor and 10 inches (25.4 cm) from the center of the two sides of the unit under test. The ambient temperature shall be 72.0 ± 1 °F (21.1 ± 0.6 °C) during the stabilization period and the test period.

Compartment Temperature Measurements:

No compartment temperature measurements are taken during the stabilization and test period.

Test Procedure:

Run the test using the SmartHQ App

1. Download the SmartHQ app on a connected device
2. Select ''Connect Appliance'' and then ''In Home Grower''
3. Follow the procedures per the SmartHQ app to set up the appliance.
4. Fill the nutrient and supply tanks with 72.0 ± 5.0 °F water.
5. Select ''Let's Start Planting'' from the main screen.
6. Select Garden 1 from the ''Select Garden'' screen
   a. Select the ''Default'' growing region.
   b. Select ''Next'' at the bottom of the screen
7. At the screen titled ''What do you want to plant in Garden x?'', select ''Choose Later''
8. Repeat this process for Garden 2 and Garden 3.
9. Select ''Start the Growing Cycle''
10. The first rotation (8 hours) is the stabilization period.
11. The next three rotations (24 hours) is the period where EP and T data are taken.

[FR Doc. 2021–24902 Filed 11–15–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Basic Energy Sciences Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open virtual meeting.

SUMMARY: This notice announces a meeting of the Basic Energy Sciences Advisory Committee (BESAC). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Monday, December 6, 2021; 11:00 a.m. to 5:00 p.m.

ADDRESSES: This meeting is open to the public. This meeting will be held digitally via Zoom. Information to participate can be found on the website closer to the meeting date at: *https://science.osti.gov/bes/besac/Meetings.*

FOR FURTHER INFORMATION CONTACT: Kerry Hochberger; Office of Basic Energy Sciences; U.S. Department of Energy; Germantown Building, 1000 Independence Avenue SW, Washington, DC 20585; Telephone: 301–903–7661 or email: *kerry.hochberger@science.doe.gov*.

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: The purpose of this Committee is to make recommendation to DOE–SC with respect to the basic energy sciences research program.

Tentative Agenda

- Call to Order, Introductions, Review of the Agenda
- News from the Office of Science
- News from the Office of Basic Energy Sciences
- Office of Science Distinguished Scientist Fellow Presentation
- Office of Science QIS Centers Presentation
- Roundtable on Foundational Science for Carbon-Neutral Hydrogen Technologies Presentation
- Panel Discussion: Science and Energy Technology Teams
- Facility Updates: LCLS, Neutron Scattering, NSRCs Presentations
- Pre-Committee of Visitors Overview: Workforce Development for Teachers and Scientists (WDTS) Presentation
- Public Comments
- Adjourn

Breaks taken as appropriate

Public Participation: The meeting is open to the public. A webcast of this meeting will be available. Please check the website below for updates and information on how to view the meeting. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Kerry Hochberger at *kerry.hochberger@science.doe.gov.* You must make your request for an oral statement at least five business days before the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule. Information about the committee can be found at: *https://science.osti.gov/bes/besac.*

Minutes: The minutes of this meeting will be available for public review on the U.S. Department of Energy's Office

of Basic Energy Sciences website at: *https://science.osti.gov/bes/besac/Meetings.*

Signed in Washington, DC, on November 9, 2021.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2021–24930 Filed 11–15–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Case No. 2021–009; EERE–2021–BT–WAV–0025]

Energy Conservation Program: Notification of Petition for Waiver of Nortek Global HVAC, LLC From the Department of Energy Central Air Conditioners and Heat Pumps Test Procedure, Notification of Denial of Interim Waiver, and Request for Comment

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notification of petition for waiver and denial of an interim waiver; request for comments.

SUMMARY: This notification announces receipt of and publishes a petition for waiver and interim waiver from Nortek Global HVAC, LLC (''Nortek''), which seeks a waiver for specified central air conditioner and heat pump basic models from the U.S. Department of Energy (''DOE'') test procedure used for determining the energy efficiency of these products. This notification also announces that DOE is declining to grant the request for an interim waiver from the test procedure for the reasons described in this notification. DOE solicits comments, data, and information concerning the petition and its suggested alternate test procedure so as to inform DOE's final decision on the waiver request.

DATES: Written comments and information are requested and will be accepted on or before December 16, 2021.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov.* Alternatively, interested persons may submit comments, identified by case number 2021–009 and Docket number EERE–2021–BT–WAV–0025, by any of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.

2. *Email: AS_Waiver_Requests@ee.doe.gov.* Include the docket number EERE–2021–BT–WAV–0025 in the subject line of the message.

No telefacsimiles (''faxes'') will be accepted. For detailed instructions on submitting comments and additional information on this process, see the **SUPPLEMENTARY INFORMATION** section of this document.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing coronavirus (''COVID–19'') pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this change poses an undue hardship, please contact Appliance Standards Program staff at (202) 586–1445 to discuss the need for alternative arrangements. Once the COVID–19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

Docket: The docket, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at *www.regulations.gov/docket?D=EERE-2021-BT-WAV-0025.* The docket web page contains instruction on how to access all documents, including public comments, in the docket. See the **SUPPLEMENTARY INFORMATION** section for information how to submit comments through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Ms. Julia Hegarty, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Email: *S_Waiver_Requests@ee.doe.gov.*

Mr. Peter Cochran, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–33, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0103. Telephone: (202) 586–9496. Email: *peter.cochran@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE is publishing Nortek's petition for waiver, pursuant to 10 CFR 430.27(b)(1)(iv), inclusive of all substantive portions thereof and absent any information for which petitioner requested treatment as confidential business information.[1] DOE invites all interested parties to submit in writing by December 16, 2021, comments and information on all aspects of the petition, including an alternate test procedure. Pursuant to 10 CFR 430.27(d), any person submitting written comments to DOE must also send a copy of such comments to the petitioner. The contact information for the petitioner is:

Matthew Lattanzi, Nortek Global HVAC, 8000 Phoenix Parkway, O'Fallon, MO 63368. Email: *matthew.lattanzi@nortek.com.*

Submitting comments via www.regulations.gov. The *www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. If this instruction is followed, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (''CBI''). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For

[1] The petition as submitted included the entire text of 10 CFR part 430 subpart B appendix M1. The reprint of the petition at the end of this notification includes only the substantive provisions of that appendix. The petition for waiver and petition for interim waiver is available in its entirety at *www.regulations.gov/docket?D=EERE-2021-BT-WAV-0025.*

information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email. Comments and documents submitted via email also will be posted to *www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable if it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. Faxes will not be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: One copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

I. Background and Authority

The Energy Policy and Conservation Act, as amended (''EPCA''),[2] authorizes DOE to regulate the energy efficiency of a number of consumer products and industrial equipment. (42 U.S.C. 6291–6317) Title III, Part B [3] of EPCA, Public Law 94–163 (42 U.S.C. 6291–6309, as codified), established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency for certain types of consumer products. These products include central air conditioners and heat pumps (''CAC/HPs''), the subject of this notification. (42 U.S.C. 6292(a)(3))

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

The Federal testing requirements consist of test procedures that manufacturers of covered products must use as the basis for: (1) Certifying to DOE that their products comply with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6295(s)), and (2) making representations about the efficiency of that product (42 U.S.C. 6293(c)). Similarly, DOE must use these test procedures to determine whether the product complies with relevant standards promulgated under EPCA. (42 U.S.C. 6295(s))

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE is required to follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

Beginning January 1, 2023, any representations, including compliance certifications, made with respect to the energy use, power, or efficiency of CAC/HPs must be based on the results of testing according to the test procedure contained in the Code of Federal Regulations (''CFR'') at 10 CFR part 430, subpart B, appendix M1, *Uniform Test Method for Measuring the Energy Consumption of Central Air Conditioners and Heat Pumps* (''Appendix M1'').

Under 10 CFR 430.27, any interested person may submit a petition for waiver from DOE's test procedure requirements. DOE will grant a waiver from the test procedure requirements if DOE determines either that the basic model for which the waiver was requested contains a design characteristic that prevents testing of the basic model according to the prescribed test procedures, or that the prescribed test procedures evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 430.27(f)(2). A petitioner must include in its petition any alternate test procedures known to the petitioner to evaluate the performance of the product type in a manner representative of the energy consumption characteristics of the basic model. 10 CFR 430.27(b)(1)(iii). DOE may grant the waiver subject the conditions, including adherence to alternate test procedures. 10 CFR 430.27(f)(2).

As soon as practicable after the granting of any waiver, DOE will publish in the **Federal Register** a notice of proposed rulemaking to amend its regulations so as to eliminate any need for the continuation of such waiver. 10 CFR 430.27(l). As soon thereafter as practicable, DOE will publish in the **Federal Register** a final rule to that effect. *Id.*

The waiver process also provides that DOE may grant an interim waiver if it appears likely that the underlying petition for waiver will be granted and/or if DOE determines that it would be desirable for public policy reasons to grant immediate relief pending a determination on the underlying petition for waiver. 10 CFR 430.27(e)(2). Within one year of issuance of an interim waiver, DOE will either: (i) Publish in the **Federal Register** a

[2] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2021).

[3] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated as Part A.

determination on the petition for waiver; or (ii) publish in the **Federal Register** a new or amended test procedure that addresses the issues presented in the waiver. 10 CFR 430.27(h)(2).

If DOE ultimately denies the petition for waiver, or if the alternate test procedure specified in the interim waiver differs from the alternate test procedure specified by DOE in a subsequent Decision and Order, DOE will provide a period of 180 days before the manufacturer is required to use the DOE test procedure or the alternate test procedure specified in the Decision and Order to make representations of energy efficiency. 10 CFR 430.27(i). When DOE amends the test procedure to address the issues presented in a waiver, the waiver will automatically terminate on the date on which use of that test procedure is required to demonstrate compliance. 10 CFR 430.27(h)(3).

II. Nortek's Petition for Waiver and Interim Waiver

By letter dated September 7, 2021,[4] Nortek filed a petition for waiver and interim waiver from the test procedure for CAC/HPs set forth in appendix M1, when effective.[5] The petition specifies the basic models to be considered under the waiver request. (Nortek, No. 1 at pp. 12–18). In its petition, Nortek asserted that appendix M1 contains errors in the calculations for capacity adjustment and power consumption for the indoor fan at part-load conditions, applicable to testing of two-stage coil-only CAC/HPs. (Nortek, No. 1 at p. 1). As such, Nortek claimed that the DOE test procedure evaluates its specified basic models in a manner unrepresentative of their true energy use; thereby providing materially inaccurate comparative data. *Id.*

Coil-only systems are indoor units that are distributed in commerce without an indoor blower or separate designated air mover. Such systems installed in the field rely on a separately installed furnace or a modular blower for indoor air movement. Because coil-only CAC/HPs do not include their own indoor fan to circulate air, appendix M1 prescribes equations that are used to calculate the assumed (*i.e.,* ''default'') power input and heat output of an average furnace fan with which the test procedure assumes the indoor coil is pared in a field installation. The resulting fan power input value is added to the electrical power consumption measured during testing. The resulting fan heat output value is subtracted from the measured cooling capacity of the CAC/HP for cooling mode tests and added to the measured heating capacity for heating mode tests. Separate fan power and fan heat equations are provided for different types of coil-only systems (*i.e.,* mobile home or space-constrained vs. ''conventional'' non-mobile home and non-space-constrained). In each equation, the measured airflow rate (in cubic feet per minute of standard air (''scfm'')) is multiplied by a defined coefficient (expressed in Watts (''W'') per 1,000 scfm (''W/1,000 scfm'') for fan power, and British Thermal Units (''Btu'') per hour (''Btu/h'') per 1,000 scfm (''Btu/h/1,000 scfm'') for fan heat), hereafter referred to as the ''default fan power coefficient'' and ''default fan heat coefficient''.

For coil-only units installed in mobile-home and space-constrained systems, appendix M1 defines a default fan power coefficient of 406 W/1,000 scfm and a default fan heat coefficient of 1,385 Btu/h/1,000 scfm. For coil-only units installed in conventional (*i.e.,* non-mobile-home and non-space-constrained) systems, appendix M1 defines a default fan power coefficient of 441 W/1,000 scfm and a default fan heat coefficient of 1,505 Btu/h/1,000 scfm.[6] (10 CFR part 430, subpart B, appendix M1, section 3.3.d) For testing of two-stage coil-only systems, appendix M1 requires testing at two load conditions: (1) Full-load, operating at full compressor stage, and (2) low-load (also referred to as part-load), operating at the lower compressor stage. The test procedure defines the relative air volume rates to use for each test. The part-load test has a lower air volume rate than the full-load test.[7] For both the default fan power coefficient and default fan heat coefficient, the same coefficient is used for both the full-load and part-load tests.

Nortek asserted that by applying the same default fan power coefficient and default fan heat coefficient to both the full-load and part-load tests, appendix M1 incorrectly establishes a linear relationship between indoor airflow and fan power (and fan heat); whereas, according to Nortek, a cubic relationship should be applied instead, citing the theoretical fan affinity laws that describe the relationship between fan power and airflow. (Nortek, No. 1 at p. 2) Nortek recommended an alternate test procedure that would define lower default fan power coefficients and default fan heat coefficients for the part-load tests, instead of applying the same coefficients to both the full-load and part-load tests, as is done in appendix M1. (Nortek, No. 1 at pp. 4–9) The lower coefficients recommended by Nortek are based on its analysis that incorporated theoretical fan power (based on fan affinity laws); estimates of fan motor efficiency (based on input from motor experts and Nortek's internal testing and experience); and estimates of the installed base of minimally efficient versus high-efficiency motor technologies (based on estimates from the 2015 energy conservation standards rulemaking). *Id.*

Nortek also requests an interim waiver from the existing DOE test procedure. DOE must review the petition for interim waiver within 45 business days of receipt of the petition. 10 CFR 430.27(e)(1)(ii). If DOE does not notify the applicant of the disposition of the petition for interim waiver, in writing, within 45 business days of receipt of the petition, the interim waiver is granted utilizing the alternate test procedure requested in the petition. *Id.* DOE will grant an interim waiver if it appears likely that the petition for waiver will be granted, and/or if DOE determines that it would be desirable for public policy reasons to grant immediate relief pending a determination of the petition for waiver. 10 CFR 430.27(e)(2).

III. Requested Alternate Test Procedure

EPCA requires that manufacturers use DOE test procedures when making representations about the energy consumption and energy consumption costs of covered products. (42 U.S.C. 6293(c)) Consistency is important when making representations about the energy efficiency of covered products, including when demonstrating compliance with applicable DOE energy conservation standards. Pursuant to 10 CFR 430.27, and after consideration of public comments on the petition, DOE may establish in a subsequent Decision and Order an alternate test procedure

[4] A petition submitted under 10 CFR 430.27 is considered ''received'' on the date it is received by DOE through DOE's established email box for receipt of waiver petitions or, if delivered by mail, on the date the waiver petition is stamped as received by the DOE. 10 CFR 430.27(e)(1)(iii).

[5] As noted, beginning January 1, 2023, any representations, including compliance certifications, made with respect to the energy use, power, or efficiency of CAC/HPs must be based on the results of testing according to the test procedure at appendix M1.

[6] For example, for a CAC/HP test conducted at an airflow rate of 1,640 scfm, the default fan power for a ''conventional'' installation would be calculated as (441 W/1,000 scfm × 1,640 scfm = 723 W); and the default fan heat would be calculated as (1,505 Btu/h/1,000 scfm × 1,640 scfm = 2,466 Btu/h).

[7] Specifically, the indoor air volume rate to be used for testing at part-load (*i.e.,* the ''cooling minimum air volume rate'') is the higher of (1) the rate specified by the installation instructions included with the unit by the manufacturer, or (2) 75 percent of the cooling full-load air volume rate (see section 3.1.4.2.c of appendix M1).

for the basic models addressed by an Interim Waiver Order.

Nortek seeks to use an alternate test procedure to test and rate the specified ducted, coil-only, two-stage CAC and HP basic models. Nortek's alternate test procedure would require the basic models of CAC/HPs identified in the petition to be tested according to the test procedure at appendix M1, as applicable, except using alternate equations in sections 3.3.d, 3.5.1, 3.7.c, and 3.9.1 for part-load test conditions. As discussed, these sections of appendix M1 are used to calculate adjustments to cooling and heating capacity and adjustments to system power consumption to account for the assumed power input of the indoor fan for coil-only systems. The alternate test procedure requested by Nortek would define lower default fan power coefficients and default fan heat coefficients for the part-load tests, instead of applying the same coefficients to both the full-load and part-load tests, as is done in appendix M1. (Nortek, No. 1 at pp. 4–9)

IV. Denial of Interim Waiver and Request for Comments

DOE has reviewed Nortek's petition for an interim waiver and the alternate test procedure requested by Nortek. In submitting a petition for waiver, a petitioner must demonstrate that the subject basic model contains one or more design characteristics which either prevent testing of the basic model according to the prescribed test procedures or cause the prescribed test procedures to evaluate the basic model in a manner so unrepresentative of its true energy and/or water consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 430.27(a)(1). In determining whether to grant a request for an interim waiver, DOE considers whether: (1) It appears likely that the petition for waiver will be granted; and/or (2) it would be desirable for public policy reasons to grant immediate relief pending a determination on the petition for waiver. 10 CFR 430.27(e)(2).

Nortek does not claim in its petition for waiver that the subject basic models contain a design characteristic that prevents testing according to DOE test procedure. Instead, Nortek claims that the prescribed test procedures evaluate its coil-only, two-stage systems in a manner so unrepresentative of their true energy characteristics as to provide materially inaccurate comparative data.

In response to this claim, DOE first notes that default fan power coefficients and default fan heat coefficients have been used for both full- and part-load operation for many years prior to DOE having considered the issue explicitly in a 2005 rulemaking. *See* 70 FR 59122, 59128 (October 11, 2005) (''October 2005 Final Rule''). The question of whether a lower default fan power coefficient should be used for part-load operation was considered in the October 2005 Final Rule. After consideration of the issue, including consideration of stakeholder comments, DOE implemented a single default coefficient value into the test procedure. *Id.* The use of a single default fan power coefficient for both full- and part-load capacity was not changed in the most recent test procedure final rule (although the value of the coefficient was updated, with different values specified for mobile home and space constrained versus non-mobile home and non-space-constrained systems). 82 FR 1426, 1452 (January 5, 2017) (''January 2017 Final Rule). In the January 2017 Final Rule, DOE adopted the recommendations, including equations to represent the assumed power input of the fan, from a working group formed to negotiate a notice of proposed rulemaking for energy conservation standards for CAC/HPs. 82 FR 1426, 1452. In comments submitted during the course of that rulemaking, manufacturers, including Nortek, expressed support for the use of a single default fan power coefficient to represent both the full- and part-load test conditions for coil-only testing. 82 FR 1426, 1452.

In its petition for waiver, Nortek claims that lower default fan power and fan heat coefficients should be applied to part-load tests. The lower coefficients recommended by Nortek are based on its analysis that incorporated theoretical fan power (based on fan affinity laws); estimates of fan motor efficiency (based on input from motor experts and Nortek's internal testing and experience); and estimates of the installed base of minimally efficient versus high-efficiency motor technologies (based on estimates from the 2015 energy conservation standards rulemaking).

In reviewing Nortek's petition and its proposed alternate test procedure, DOE notes that Nortek's analysis is theoretical, based on the fan laws and estimates of motor efficiencies that Nortek described are based on input from motor experts and its internal testing and experience. Real-world fan motor efficiency can deviate, however, from theoretically predicted values due to a myriad of factors, which do not appear to be reflected in Nortek's analytically-derived estimates. Nortek did not submit any data demonstrating that its fan efficiency estimates are representative of field performance of furnace fans. As such, Nortek has not demonstrated that the fan efficiency values suggested in the petition would be more representative than the values specified in the current DOE test procedures. In contrast, the analysis conducted by DOE to develop the default indoor fan wattage for coil-only systems for appendix M1 was based on test data and product datasheets indicative of the performance of furnace fans in actual installation. *Id.* at 1451–1452. This data set and analytical approach was the same used to develop fan wattage levels when operating at the reference system external static pressure values for the purposes of determining Fan Energy Rating for furnace fans. (79 FR 499, 506; January 3, 2014). DOE believes that any consideration of an alternative fan wattage factor for part-load operation for coil-only systems should be based on a similarly rigorous analysis that includes real-world test data. Absent such data, DOE is unable to conclude that Nortek's petition for waiver will likely be granted. Further, DOE does not find that public policy reasons weigh in favor of granting immediate relief pending a determination on the petition for waiver. As discussed previously, use of the same default fan power and fan heat coefficients for full-load and part-load tests has been the industry standard for many years and manufacturers expressed their support for this approach in the January 2017 Final Rule. For these reasons, DOE is denying the interim waiver and requesting comment.

DOE makes decisions on waivers and interim waivers for only those basic models specifically set out in the petition, not future models that may be manufactured by the petitioner. Nortek may submit a new or amended petition for waiver and request for grant of interim waiver, as appropriate, for additional basic models of ducted, coil-only, two-stage central air conditioner and heat pumps.

While DOE declines to approve the use of Nortek's suggested alternate test procedure in an interim waiver at this time, DOE may consider including an alternate procedure in a subsequent Decision and Order. DOE solicits comments from interested parties on all aspects of the petition, including any alternate test procedure.

Signing Authority

This document of the Department of Energy was signed on November 9, 2021, by Kelly Speakes-Backman, Principal Deputy Assistant Secretary

and Acting Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 9, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

Petition for Waiver and Interim Waiver

Date: September 7, 2021

U.S. Department of Energy
Building Technologies Program
1000 Independence Avenue SW,
Mailstop EE–5B
Washington, DC 20585–0121

Via email to: *AS_Waiver_Requests@ee.doe.gov*

Re: Petitions for Waiver and Interim Waiver on M1 Test Procedure for 2-Stage Central Air Conditioners and Air Source Heat Pumps

Dear Sir/Ms.: Nortek Global HVAC, LLC (Nortek) respectfully submits petitions for waiver and interim waiver to the Department of Energy (DOE) from certain provisions in the federal test procedure for central air conditioners and heat pumps in Appendix M1 to Subpart B of 10 CFR part 430 (Appendix M1). Specifically, Nortek is requesting waivers for ducted, coil only, 2 stage, central air conditioners, and air source heat pumps.

Nortek Global HVAC, LLC (Nortek) has been a world-class manufacturer of heating and cooling equipment for 100 years. We pride ourselves in upholding our mission of *creating a better tomorrow, every day.* As a company, we can achieve these standards through a unique combination of innovation, product performance, and responsive support. Nortek Global HVAC and its subsidiaries build and sell HVAC systems under the Maytag, Broan, Frigidaire, NuTone, and Reznor brands, among others.

I. Introduction

The federal test procedure in Appendix M1 indicates tests for coil only, 2-stage, central air conditioners, and air source heat pumps. However, there are errors in the required calculations for capacity reduction and increasing power usage during low stage operation. These errors cause the prescribed test procedure to evaluate the basic model in a manner unrepresentative of its true energy use; thereby, providing materially inaccurate comparative data.[1]

II. List of Basic Models

Per 10 CFR 430.27(b)(i), Nortek is providing, in appendix I of this petition, a list of basic models for which Nortek is seeking a waiver and interim waiver from the Appendix M1 test procedure.

III. List of Manufacturers

Per 10 CFR 430.27(b)(ii), Nortek is providing, in appendix II of this petition, a list of other manufacturers known to Nortek that distribute into commerce basic models similar in design characteristics to the basic models that are the subject of this petition.

IV. Grounds for Petition of Interim Waiver and Waiver

Appendix M1 Sections 3.3.d, 3.5.1, 3.7.c, and 3.9.1 provide equations for decreasing system capacity and increasing power usage for mobile home, space constrained, non-mobile home, and non-space constrained, ducted, two-stage, coil only systems. However, these equations are in error for low-stage operation. M1 incorrectly establishes a linear relationship between high stage and low stage operation for decreasing $\dot{Q}_c^k(T)$ and increasing $\dot{E}_c^k(T)$ where a cubic relationship should be applied. Fan affinity laws are very clear and stipulate for a constant wheel diameter the relationship between power and air flow rate is:

$P_1/P_2 = (q_1/q_2)^3$

where:

P_1 = low stage power
P_2 = high stage power
q_1 = low stage air flow
q_2 = high stage air flow

Source: *https://www.engineeringtoolbox.com/fan-affinity-laws-d_196.html.*

These errors amount to a failure in applying basic engineering principles that are fundamental to the design of HVAC systems. Furthermore, under the prescribed test procedure, a penalty of as much as 1 SEER2 point is realized depending on the application. One SEER2 point is substantial and renders the performance data incomparable to other systems (*e.g.,* single stage, variable speed).

Nortek understands that fan affinity laws apply only to the fan shaft power and do not account for the efficiency of the motor driving the fan. To account for motor efficiencies, Nortek has developed the below data based on input from motor experts and decades of internal testing and experience. This data was reviewed by a major motor supplier to the HVAC industry, and the efficiency estimates were confirmed to be reasonable but conservative relative to realized efficiency in the application.

Air flow %	PSC Eff estimate %	ECM Eff estimate %
100	62.6	80.0
95	59.8	79.0
90	55.2	79.0
85	53.1	79.0
80	50.0	78.5
75	46.9	78.0

The 2015 ASRAC negotiated rule for Energy Conservation Standards for Central Air Conditioners and Heat Pumps estimated the installed base for PSC and ECM motor to be 77% and 23% respectively.[2] Nortek viewed these estimates as conservative in 2015. And, considering the Fan Efficiency Rating (FER) regulation was implemented in July 2019, it's obvious the installed base is now much more concentrated in ECM motors. However, in the interests of maintaining a conservative approach to this wavier and interim waiver request, Nortek is maintaining the 77%/23% estimates for the purposes of developing blended watts/scfm values for a range of airflows. See below table which represents our recommendations for non-mobile home, non-space constrained, ducted, coil-only, central air conditioning and air source heat pump tests.

[1] See 10 CFR 430.27(a)(1).

[2] *https://www.regulations.gov/document/EERE-2014-BT-STD-0048-0044CAC_DefaultFanPowerDRAFTAnalysisSummary_2015-09-16_public.*

Air flow %	Fan only watts/SCFM (excludes motor)	PSC Eff estimate %	PSC+Fan watts/SCFM	% PSC	ECM Eff estimate %	ECM+fan watts/SCFM	% ECM	Blended watts/SCFM
100	0.290	62.6	0.464	77	80.0	0.363	23	0.441
95	0.266	59.8	0.445	77	79.0	0.337	23	0.420
90	0.226	55.2	0.410	77	79.0	0.287	23	0.382
85	0.191	53.1	0.359	77	79.0	0.241	23	0.332
80	0.159	50.0	0.318	77	78.5	0.203	23	0.291
75	0.131	46.9	0.279	77	78.0	0.168	23	0.254

See below table which represents our recommendations mobile home, space constrained, ducted, coil-only central air conditioning and air source heat pump tests.

Air flow %	Fan only watts/OSCFM (excludes motor)	PSC Eff estimate %	PSC+Fan watts/SCFM	% PSC	ECM Eff estimate %	ECM+fan watts/SCFM	% ECM	Blended watts/SCFM
100	0.267	62.6	0.427	77	80.0	0.334	23	0.406
95	0.229	59.8	0.383	77	79.0	0.290	23	0.362
90	0.195	55.2	0.353	77	79.0	0.247	23	0.329
85	0.164	53.1	0.309	77	79.0	0.208	23	0.286
80	0.137	50.0	0.274	77	78.5	0.174	23	0.251
75	0.113	46.9	0.240	77	78.0	0.145	23	0.218

V. Proposed Alternative Test Procedure

As required by 10 CFR 430.27(b)(iii), Nortek is providing the proposed revisions below to Appendix M1 as the alternative to evaluate the performance of the basic models listed in Appendix I of this petition. In addition, a redline markup with these revisions of Appendix M1 is included as Appendix III.

Section 3.3.d for mobile home and space constrained ducted coil-only systems

BILLING CODE 6450–01–P

For low stage operation, revise equation $\frac{1385\ Btu/h}{1000\ scfm} * \dot{\bar{V}}_s$ to:

3.412 BTU/h * P * $\dot{\bar{V}}_s$

And, for low stage operation, revise equation $\frac{406\ W}{1000\ scfm} * \dot{\bar{V}}_s$ to:

P * $\dot{\bar{V}}_s$.

Where P is the power consumption rate corresponding to the minimum airflow rate per the table below. Calculate W/scfm utilizing linear interpolation for minimum airflow values in between the values indicated.

Air Flow %	Blended Watts/SCFM
100%	0.406
95%	0.362
90%	0.329
85%	0.286
80%	0.251
75%	0.218

Section 3.3.d For non-mobile home, non-space constrained home ducted coil-only systems

For low stage operation, revise equation $\frac{1505\ Btu/h}{1000\ scfm} * \dot{\bar{V}}_s$ to:

3.412 BTU/h * P * $\dot{\bar{V}}_s$.

And, for low stage operation, revise equation $\frac{441\ W}{1000\ scfm} * \dot{\bar{V}}_s$ to:

P * $\dot{\bar{V}}_s$

Where P is the power consumption rate corresponding to the minimum airflow rate per the table below. Calculate W/scfm utilizing linear interpolation for minimum airflow the values in between values indicated.

Air Flow %	Blended Watts/SCFM
100%	0.441
95%	0.420
90%	0.382
85%	0.332

80%	0.291
75%	0.254

Section 3.5.1 For mobile home and space constrained ducted coil-only systems

For low stage operation, revise equation $\frac{1385\ Btu/h}{1000\ scfm} * \dot{\overline{V}}_s * \left[\tau_2 - \tau_1\right]$ to:

3.412 BTU/h * P * $\dot{\overline{V}}_s$ *[τ_2 -τ_1]

And, for low stage operation, revise equation $\frac{406W}{1000scfm} * \dot{\overline{V}}_s * [\tau_2 - \tau_1]$ to:

P * $\dot{\overline{V}}_s$ *[τ_2 -τ_1]

Where P is the power consumption rate corresponding to the minimum airflow rate per the table below. Calculate W/scfm utilizing linear interpolation for minimum airflow values in between the values indicated.

Air Flow %	Blended Watts/SCFM
100%	0.406
95%	0.362
90%	0.329
85%	0.286
80%	0.251
75%	0.218

Section 3.5.1 For non-mobile home, non-space constrained home ducted coil-only systems

For low stage operation, revise equation $\frac{1505\ Btu/h}{1000\ scfm} * \dot{\overline{V}}_s * [\tau_2 - \tau_1]$ to:

3.412 BTU/h * P * $\dot{\overline{V}}_s$ *[τ_2 -τ_1]

And, for low stage operation, revise equation $\frac{441W}{1000scfm} * \dot{\overline{V}}_s * [\tau_2 - \tau_1]$ to:

P * $\dot{\overline{V}}_s$ *[τ_2 -τ_1]

Where P is the power consumption rate corresponding to the minimum airflow rate per the table below. Calculate W/scfm utilizing linear interpolation for minimum airflow values in between the values indicated.

Air Flow %	Blended Watts/SCFM

100%	0.441
95%	0.420
90%	0.382
85%	0.332
80%	0.291
75%	0.254

Section 3.7.c For mobile home and space constrained coil-only heat pump systems

For low stage operation, revise equation $\frac{1385\ Btu/h}{1000\ scfm} * \dot{V}_s$ to:

3.412 BTU/h * P * $\dot{V}_s$

And, for low stage operation, revise equation $\frac{406\ W}{1000\ scfm} * \dot{V}_s$ to:

P * $\dot{V}_s$.

Where P is the power consumption rate corresponding to the minimum airflow rate per the table below. Calculate W/scfm utilizing linear interpolation for minimum airflow values in between the values indicated.

Air Flow %	Blended Watts/SCFM
100%	0.406
95%	0.362
90%	0.329
85%	0.286
80%	0.251
75%	0.218

Section 3.7.c For non-mobile home, non-space constrained coil-only heat pump systems

For low stage operation, revise equation $\frac{1505\ Btu/h}{1000\ scfm} * \dot{V}_s$ to:

3.412 BTU/h * P * $\dot{V}_s$

And, for low stage operation, revise equation $\frac{441\ W}{1000\ scfm} * \dot{V}_s$ to:

P * $\dot{V}_s$

Where P is the power consumption rate corresponding to the minimum airflow rate per the table below. Calculate W/scfm utilizing linear interpolation for minimum airflow values in between the values indicated.

Air Flow %	Blended Watts/SCFM
100%	0.441
95%	0.420
90%	0.382
85%	0.332
80%	0.291
75%	0.254

Section 3.9.1 For mobile home and space constrained coil-only heat pump systems

For low stage operation, revise equation $\frac{1385\ Btu/h}{1000\ scfm} * \bar{V}_s$ to:

3.412 BTU/h * P * $\bar{V}_s$

And, for low stage operation, revise equation $\frac{406\ W}{1000\ scfm} * \bar{V}_s$ to:

P * $\bar{V}_s$.

Where P is the power consumption rate corresponding to the minimum airflow rate per the table below. Calculate W/scfm utilizing linear interpolation for minimum airflow values in between the values indicated.

Air Flow %	Blended Watts/SCFM
100%	0.406
95%	0.362
90%	0.329
85%	0.286
80%	0.251
75%	0.218

Section 3.9.1 For non-mobile home, non-space constrained coil-only heat pump systems

For low stage operation, revise equation $\frac{1505\ Btu/h}{1000\ scfm} * \bar{V}_s$ to:

3.412 BTU/h * P * $\bar{V}_s$

And, for low stage operation, revise equation $\frac{441\,W}{1000\,scfm} * \dot{\bar{V}}_s$ to:

$$P * \dot{\bar{V}}_s$$

BILLING CODE 6450–01–C

Where P is the power consumption rate corresponding to the minimum airflow rate per the table below. Calculate W/scfm utilizing linear interpolation for minimum airflow values in between the values indicated.

Air flow %	Blended watts/SCFM
100	0.441
95	0.420
90	0.382
85	0.332
80	0.291
75	0.254

VI. Petitions for Waiver and Interim Waiver

Per 10 CFR part 430.27(b)(2), Nortek is applying for a waiver and interim waiver of the applicable test procedure requirements for the basic models listed in Appendix I.

Given the fundamental engineering technical errors regarding the equations for capacity reduction and increasing power usage for low stage operation, Nortek contends the petition for waiver is likely to be granted. Without waiver relief, Nortek will be forced to make representations of efficiency (SEER2) that Nortek knows are understated by almost a full SEER2 point resulting in incomparable performance data versus other systems (*e.g.,* single stage, variable speed). Nortek respectfully requests immediate relief (interim waiver) pending a determination of the petition for waiver.

In addition, Nortek will suffer financial harm if DOE does not grant its waiver and interim waiver request. Without an interim waiver, Nortek will be forced into overdesigning its twostage central air conditioning systems and air source heat pumps by as much as a full SEER2 point depending on application. Furthermore, Nortek estimates this overdesign to add an incremental cost of approximately [Redacted] per unit. To the consumer, a [Redacted] incremental manufacturing cost adder amounts to approximately [Redacted] given the multiple steps in the distribution channel. Nortek urges DOE to consider the public relations difficulties of unnecessarily adding incremental cost and misrepresenting the efficiency of these air conditioners to the public.

VII. Closing

Industry and AHRI are aware of the technical error described in this waiver request. And, AHRI has formed a working group to amend 2023 AHRI Standard 210/240 (Performance Rating for Unitary Air-Conditioning and Air-Source Heat Pump Equipment). However, although the proposed amendments are fundamentally aligned with Nortek's waiver and interim waiver request, Nortek does not believe the 210/240 amendment process and likely subsequent DOE test procedure amendments can be completed in sufficient time to provide Nortek with opportunity to develop these systems in time to meet the January 1, 2023, implementation compliance date for central air conditioning and air source heat pump systems. Nortek is currently developing these systems and requires certainty regarding this waiver and interim waiver to ensure implementation in our product designs in time for the January 1, 2023, compliance date for central air-conditioning and air-source heat pumps.

Nortek respectfully requests DOE grant its petitions for waiver and interim waiver of the M1 test procedure for the models listed in Appendix I. We further request an expedited determination of these waivers so that Nortek can promptly continue development of these systems to meet the January 1, 2023, SEER2 energy conservation standard implementation date. If further information is needed to assist DOE in its determination of these waivers, please contact Matt Lattanzi at *matt.lattanzi@nortek.com* (314–604–3996).

The unredacted version of this waiver and interim waiver request contains confidential commercial information within the meaning of 5 U.S.C. 552(b)(4) and are protected from disclosure under 18 U.S.C. 1905. Pursuant to 10 CFR 429.7, Nortek requests that this submission be treated as confidential and not disclosed pursuant to any FOIA request, and declares that: (1) Such information is customarily treated as confidential within the industry because its public release would cause competitive injury; (2) such information is not generally known by or available from other sources; (3) such information has not previously been made available to others without obligation concerning the information's confidentiality; (4) public disclosure of the information would result in competitive injury to Nortek by allowing competitors to learn information about Nortek's sales volume; (5) such information will not lose its confidential nature due to the passage of time; and (6) disclosure of such information would be contrary to the public interest because it would undermine free and open competition for the sales of covered products, which benefits consumers.

Sincerely,

/s/

Matthew H. Lattanzi,
Senior Director of Regulatory and Legislative Affairs, Nortek Global HVAC, LLC, matt.lattanzi@nortek.com.

cc:

Appendix I

The interim waiver and waiver requests apply to the following basic models:

Basic model No.	Brand	Outdoor unit	Indoor unit
SA3BE4M1SN60K	MAYTAG	CSA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV
SA3BE4M1SN60K	MAYTAG	CSA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	MAYTAG	CSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	MAYTAG	CSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BE4M1SN60K	AC PRO	FSA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV
SA3BE4M1SN60K	AC PRO	FSA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	AC PRO	FSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	AC PRO	FSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BE4M1SN60K	BROAN	FSA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV

Basic model No.	Brand	Outdoor unit	Indoor unit
SA3BE4M1SN60K	BROAN	FSA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	BROAN	FSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	BROAN	FSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BE4M1SN60K	FRIGIDAIRE	FSA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV
SA3BE4M1SN60K	FRIGIDAIRE	FSA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	FRIGIDAIRE	FSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	FRIGIDAIRE	FSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BE4M1SN60K	NUTONE	FSA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV
SA3BE4M1SN60K	NUTONE	FSA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	NUTONE	FSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	NUTONE	FSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BE4M1SN60K	ONYX	FSA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV
SA3BE4M1SN60K	ONYX	FSA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	ONYX	FSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	ONYX	FSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BE4M1SN60K	MAYTAG	PSA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV
SA3BE4M1SN60K	MAYTAG	PSA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	MAYTAG	PSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	MAYTAG	PSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BE4M1SN60K	NORTEK GLOBAL HVAC LLC	SA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV
SA3BE4M1SN60K	NORTEK GLOBAL HVAC LLC	SA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	NORTEK GLOBAL HVAC LLC	SA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	NORTEK GLOBAL HVAC LLC	SA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BE4M1SN60K	AIRTEMP	VSA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV
SA3BE4M1SN60K	AIRTEMP	VSA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	AIRTEMP	VSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	AIRTEMP	VSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BE4M1SN60K	ALL PRO	VSA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV
SA3BE4M1SN60K	ALL PRO	VSA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	ALL PRO	VSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	ALL PRO	VSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BE4M1SN60K	AireForce	WSA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV
SA3BE4M1SN60K	AireForce	WSA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	AireForce	WSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	AireForce	WSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BE4M1SN60K	FRIGIDAIRE	WSA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV
SA3BE4M1SN60K	FRIGIDAIRE	WSA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	FRIGIDAIRE	WSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	FRIGIDAIRE	WSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BE4M1SN60K	GIBSON	WSA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV
SA3BE4M1SN60K	GIBSON	WSA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	GIBSON	WSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	GIBSON	WSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BE4M1SN60K	MAMMOTH	WSA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV
SA3BE4M1SN60K	MAMMOTH	WSA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	MAMMOTH	WSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	MAMMOTH	WSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BE4M1SN60K	NUTONE	WSA3BE4M1SN60K	C74B(A,H)M060(C,U)-C+TXV
SA3BE4M1SN60K	NUTONE	WSA3BE4M1SN60K	C74B(A,H)M060(C,U)-D+TXV
SA3BE4M1SN60K	NUTONE	WSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-C
SA3BE4M1SN60K	NUTONE	WSA3BE4M1SN60K	C74B(A,H)MX60(C,U)-D
SA3BF4M2SN24K	MAYTAG	CSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-A
SA3BF4M2SN24K	MAYTAG	CSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-B
SA3BF4M2SN24K	AC PRO	FSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-A
SA3BF4M2SN24K	AC PRO	FSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-B
SA3BF4M2SN24K	AIREFORCE	FSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-A
SA3BF4M2SN24K	AIREFORCE	FSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-B
SA3BF4M2SN24K	BROAN	FSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-A
SA3BF4M2SN24K	BROAN	FSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-B
SA3BF4M2SN24K	FRIGIDAIRE	FSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-A
SA3BF4M2SN24K	FRIGIDAIRE	FSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-B
SA3BF4M2SN24K	NUTONE	FSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-A
SA3BF4M2SN24K	NUTONE	FSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-B
SA3BF4M2SN24K	ONYX	FSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-A
SA3BF4M2SN24K	ONYX	FSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-B
SA3BF4M2SN24K	MAYTAG	PSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-A
SA3BF4M2SN24K	MAYTAG	PSA3BF4M2SN24K	C74B(A,H)MX24(C,U)-B
SA3BF4M2SN24K	NORTEK GLOBAL HVAC LLC	SA3BF4M2SN24K	C74B(A,H)MX24(C,U)-A
SA3BF4M2SN24K	NORTEK GLOBAL HVAC LLC	SA3BF4M2SN24K	C74B(A,H)MX24(C,U)-B
SA3BF4M2SN36K	MAYTAG	CSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-B
SA3BF4M2SN36K	MAYTAG	CSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-C
SA3BF4M2SN36K	AC PRO	FSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-B
SA3BF4M2SN36K	AC PRO	FSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-C
SA3BF4M2SN36K	AIREFORCE	FSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-B

Basic model No.	Brand	Outdoor unit	Indoor unit
SA3BF4M2SN36K	AIREFORCE	FSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-C
SA3BF4M2SN36K	BROAN	FSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-B
SA3BF4M2SN36K	BROAN	FSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-C
SA3BF4M2SN36K	FRIGIDAIRE	FSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-B
SA3BF4M2SN36K	FRIGIDAIRE	FSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-C
SA3BF4M2SN36K	NUTONE	FSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-B
SA3BF4M2SN36K	NUTONE	FSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-C
SA3BF4M2SN36K	ONYX	FSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-B
SA3BF4M2SN36K	ONYX	FSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-C
SA3BF4M2SN36K	MAYTAG	PSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-B
SA3BF4M2SN36K	MAYTAG	PSA3BF4M2SN36K	C74B(A,H)MX36(C,U)-C
SA3BF4M2SN36K	NORTEK GLOBAL HVAC LLC	SA3BF4M2SN36K	C74B(A,H)MX36(C,U)-B
SA3BF4M2SN36K	NORTEK GLOBAL HVAC LLC	SA3BF4M2SN36K	C74B(A,H)MX36(C,U)-C
SA3BF4M2SN48K	MAYTAG	CSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-C
SA3BF4M2SN48K	MAYTAG	CSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-D
SA3BF4M2SN48K	AC PRO	FSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-C
SA3BF4M2SN48K	AC PRO	FSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-D
SA3BF4M2SN48K	AIREFORCE	FSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-C
SA3BF4M2SN48K	AIREFORCE	FSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-D
SA3BF4M2SN48K	BROAN	FSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-C
SA3BF4M2SN48K	BROAN	FSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-D
SA3BF4M2SN48K	FRIGIDAIRE	FSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-C
SA3BF4M2SN48K	FRIGIDAIRE	FSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-D
SA3BF4M2SN48K	NUTONE	FSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-C
SA3BF4M2SN48K	NUTONE	FSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-D
SA3BF4M2SN48K	ONYX	FSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-C
SA3BF4M2SN48K	ONYX	FSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-D
SA3BF4M2SN48K	MAYTAG	PSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-C
SA3BF4M2SN48K	MAYTAG	PSA3BF4M2SN48K	C74B(A,H)MX48(C,U)-D
SA3BF4M2SN48K	NORTEK GLOBAL HVAC LLC	SA3BF4M2SN48K	C74B(A,H)MX48(C,U)-C
SA3BF4M2SN48K	NORTEK GLOBAL HVAC LLC	SA3BF4M2SN48K	C74B(A,H)MX48(C,U)-D
SA3BF4M2SN60K	MAYTAG	CSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-C
SA3BF4M2SN60K	MAYTAG	CSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-D
SA3BF4M2SN60K	AC PRO	FSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-C
SA3BF4M2SN60K	AC PRO	FSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-D
SA3BF4M2SN60K	AIREFORCE	FSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-C
SA3BF4M2SN60K	AIREFORCE	FSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-D
SA3BF4M2SN60K	BROAN	FSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-C
SA3BF4M2SN60K	BROAN	FSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-D
SA3BF4M2SN60K	FRIGIDAIRE	FSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-C
SA3BF4M2SN60K	FRIGIDAIRE	FSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-D
SA3BF4M2SN60K	NUTONE	FSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-C
SA3BF4M2SN60K	NUTONE	FSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-D
SA3BF4M2SN60K	ONYX	FSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-C
SA3BF4M2SN60K	ONYX	FSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-D
SA3BF4M2SN60K	MAYTAG	PSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-C
SA3BF4M2SN60K	MAYTAG	PSA3BF4M2SN60K	C74B(A,H)MX60(C,U)-D
SA3BF4M2SN60K	NORTEK GLOBAL HVAC LLC	SA3BF4M2SN60K	C74B(A,H)MX60(C,U)-C
SA3BF4M2SN60K	NORTEK GLOBAL HVAC LLC	SA3BF4M2SN60K	C74B(A,H)MX60(C,U)-D
SH3BF4M2SX24K	AC PRO	FSH3BF4M2SX24K	C74B(A,H)MX24(C,U)-A
SH3BF4M2SX24K	AC PRO	FSH3BF4M2SX24K	C74B(A,H)MX24(C,U)-B
SH3BF4M2SX24K	AIREFORCE	FSH3BF4M2SX24K	C74B(A,H)MX24(C,U)-A
SH3BF4M2SX24K	AIREFORCE	FSH3BF4M2SX24K	C74B(A,H)MX24(C,U)-B
SH3BF4M2SX24K	BROAN	FSH3BF4M2SX24K	C74B(A,H)MX24(C,U)-A
SH3BF4M2SX24K	BROAN	FSH3BF4M2SX24K	C74B(A,H)MX24(C,U)-B
SH3BF4M2SX24K	FRIGIDAIRE	FSH3BF4M2SX24K	C74B(A,H)MX24(C,U)-A
SH3BF4M2SX24K	FRIGIDAIRE	FSH3BF4M2SX24K	C74B(A,H)MX24(C,U)-B
SH3BF4M2SX24K	NUTONE	FSH3BF4M2SX24K	C74B(A,H)MX24(C,U)-A
SH3BF4M2SX24K	NUTONE	FSH3BF4M2SX24K	C74B(A,H)MX24(C,U)-B
SH3BF4M2SX24K	ONYX	FSH3BF4M2SX24K	C74B(A,H)MX24(C,U)-A
SH3BF4M2SX24K	ONYX	FSH3BF4M2SX24K	C74B(A,H)MX24(C,U)-B
SH3BF4M2SX24K	MAYTAG	PSH3BF4M2SX24K	C74B(A,H)MX24(C,U)-A
SH3BF4M2SX24K	MAYTAG	PSH3BF4M2SX24K	C74B(A,H)MX24(C,U)-B
SH3BF4M2SX24K	NORTEK GLOBAL HVAC LLC	SH3BF4M2SX24K	C74B(A,H)MX24(C,U)-A
SH3BF4M2SX24K	NORTEK GLOBAL HVAC LLC	SH3BF4M2SX24K	C74B(A,H)MX24(C,U)-B
SH3BF4M2SX36K	AC PRO	FSH3BF4M2SX36K	C74B(A,H)MX36(C,U)-B
SH3BF4M2SX36K	AC PRO	FSH3BF4M2SX36K	C74B(A,H)MX36(C,U)-C
SH3BF4M2SX36K	AIREFORCE	FSH3BF4M2SX36K	C74B(A,H)MX36(C,U)-B
SH3BF4M2SX36K	AIREFORCE	FSH3BF4M2SX36K	C74B(A,H)MX36(C,U)-C
SH3BF4M2SX36K	BROAN	FSH3BF4M2SX36K	C74B(A,H)MX36(C,U)-B
SH3BF4M2SX36K	BROAN	FSH3BF4M2SX36K	C74B(A,H)MX36(C,U)-C
SH3BF4M2SX36K	FRIGIDAIRE	FSH3BF4M2SX36K	C74B(A,H)MX36(C,U)-B
SH3BF4M2SX36K	FRIGIDAIRE	FSH3BF4M2SX36K	C74B(A,H)MX36(C,U)-C
SH3BF4M2SX36K	NUTONE	FSH3BF4M2SX36K	C74B(A,H)MX36(C,U)-B

Basic model No.	Brand	Outdoor unit	Indoor unit
SH3BF4M2SX36K	NUTONE	FSH3BF4M2SX36K	C74B(A,H)MX36(C,U)-C
SH3BF4M2SX36K	ONYX	FSH3BF4M2SX36K	C74B(A,H)MX36(C,U)-B
SH3BF4M2SX36K	ONYX	FSH3BF4M2SX36K	C74B(A,H)MX36(C,U)-C
SH3BF4M2SX36K	MAYTAG	PSH3BF4M2SX36K	C74B(A,H)MX36(C,U)-B
SH3BF4M2SX36K	MAYTAG	PSH3BF4M2SX36K	C74B(A,H)MX36(C,U)-C
SH3BF4M2SX36K	NORTEK GLOBAL HVAC LLC	SH3BF4M2SX36K	C74B(A,H)MX36(C,U)-B
SH3BF4M2SX36K	NORTEK GLOBAL HVAC LLC	SH3BF4M2SX36K	C74B(A,H)MX36(C,U)-C
SH3BF4M2SX48K	AC PRO	FSH3BF4M2SX48K	C74B(A,H)MX48(C,U)-C
SH3BF4M2SX48K	AC PRO	FSH3BF4M2SX48K	C74B(A,H)MX48(C,U)-D
SH3BF4M2SX48K	AIREFORCE	FSH3BF4M2SX48K	C74B(A,H)MX48(C,U)-C
SH3BF4M2SX48K	AIREFORCE	FSH3BF4M2SX48K	C74B(A,H)MX48(C,U)-D
SH3BF4M2SX48K	BROAN	FSH3BF4M2SX48K	C74B(A,H)MX48(C,U)-C
SH3BF4M2SX48K	BROAN	FSH3BF4M2SX48K	C74B(A,H)MX48(C,U)-D
SH3BF4M2SX48K	FRIGIDAIRE	FSH3BF4M2SX48K	C74B(A,H)MX48(C,U)-C
SH3BF4M2SX48K	FRIGIDAIRE	FSH3BF4M2SX48K	C74B(A,H)MX48(C,U)-D
SH3BF4M2SX48K	NUTONE	FSH3BF4M2SX48K	C74B(A,H)MX48(C,U)-C
SH3BF4M2SX48K	NUTONE	FSH3BF4M2SX48K	C74B(A,H)MX48(C,U)-D
SH3BF4M2SX48K	ONYX	FSH3BF4M2SX48K	C74B(A,H)MX48(C,U)-C
SH3BF4M2SX48K	ONYX	FSH3BF4M2SX48K	C74B(A,H)MX48(C,U)-D
SH3BF4M2SX48K	MAYTAG	PSH3BF4M2SX48K	C74B(A,H)MX48(C,U)-C
SH3BF4M2SX48K	MAYTAG	PSH3BF4M2SX48K	C74B(A,H)MX48(C,U)-D
SH3BF4M2SX48K	NORTEK GLOBAL HVAC LLC	SH3BF4M2SX48K	C74B(A,H)MX48(C,U)-C
SH3BF4M2SX48K	NORTEK GLOBAL HVAC LLC	SH3BF4M2SX48K	C74B(A,H)MX48(C,U)-D
SH3BF4M2SX60K	AC PRO	FSH3BF4M2SX60K	C74B(A,H)MX60(C,U)-C
SH3BF4M2SX60K	AC PRO	FSH3BF4M2SX60K	C74B(A,H)MX60(C,U)-D
SH3BF4M2SX60K	AIREFORCE	FSH3BF4M2SX60K	C74B(A,H)MX60(C,U)-C
SH3BF4M2SX60K	AIREFORCE	FSH3BF4M2SX60K	C74B(A,H)MX60(C,U)-D
SH3BF4M2SX60K	BROAN	FSH3BF4M2SX60K	C74B(A,H)MX60(C,U)-C
SH3BF4M2SX60K	BROAN	FSH3BF4M2SX60K	C74B(A,H)MX60(C,U)-D
SH3BF4M2SX60K	FRIGIDAIRE	FSH3BF4M2SX60K	C74B(A,H)MX60(C,U)-C
SH3BF4M2SX60K	FRIGIDAIRE	FSH3BF4M2SX60K	C74B(A,H)MX60(C,U)-D
SH3BF4M2SX60K	NUTONE	FSH3BF4M2SX60K	C74B(A,H)MX60(C,U)-C
SH3BF4M2SX60K	NUTONE	FSH3BF4M2SX60K	C74B(A,H)MX60(C,U)-D
SH3BF4M2SX60K	ONYX	FSH3BF4M2SX60K	C74B(A,H)MX60(C,U)-C
SH3BF4M2SX60K	ONYX	FSH3BF4M2SX60K	C74B(A,H)MX60(C,U)-D
SH3BF4M2SX60K	MAYTAG	PSH3BF4M2SX60K	C74B(A,H)MX60(C,U)-C
SH3BF4M2SX60K	MAYTAG	PSH3BF4M2SX60K	C74B(A,H)MX60(C,U)-D
SH3BF4M2SX60K	NORTEK GLOBAL HVAC LLC	SH3BF4M2SX60K	C74B(A,H)MX60(C,U)-C
SH3BF4M2SX60K	NORTEK GLOBAL HVAC LLC	SH3BF4M2SX60K	C74B(A,H)MX60(C,U)-D

Appendix II

The following are manufacturers of other basic models distributed in commerce in the United States and known to Nortek to incorporate design characteristics similar to those found in the basic models that are the subject of the petition for interim waiver and waiver:

- Aaon
- Advanced Distributor Products, LLC
- Allied Air Enterprise, LLC
- Allstyle Coil Company
- Aspen Manufacturing, LLC
- Bosch Thermotechnology Corp
- Carrier Corporation
- ECR International
- Fujitsu General America, Inc.
- GD Midea Heating & Ventilating Equipment Co., LtD.
- Johnson Controls, Inc.
- Lennox International Inc.
- LG Electronics U.S.A., Inc.
- Mitsubishi Electric Cooling and Heating
- Mortex Products, Inc.
- National Comfort Products
- Rheem Manufacturing Company
- Samsung Electronics Co. Ltd.
- Trane Technologies
- Unico, Inc.

[FR Doc. 2021–24903 Filed 11–15–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meetings

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

TIME AND DATE: November 18, 2021, 10:00 a.m.

PLACE: Open to the public via audio webcast only. Join FERC online to listen live at *http://ferc.capitolconnection.org/.*

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

* NOTE—Items listed on the agenda may be deleted without further notice.

1084TH—MEETING, OPEN MEETING

[November 18, 2021, 10:00 a.m.]

Item No.	Docket No.	Company
	Administrative	
A–1	AD22–1–000	Agency Administrative Matters.
A–2	AD22–2–000	Customer Matters, Reliability, Security and Market Operations.

1084TH—MEETING, OPEN MEETING—Continued

[November 18, 2021, 10:00 a.m.]

Item No.	Docket No.	Company
A–3	AD07–13–015	FY 2021 Report on Enforcement.
	Electric	
E–1	RM22–2–000	Reactive Power Capability Compensation.
E–2	OMITTED.	
E–3	ER21–2838–001	Public Service Company of Colorado.
E–4	ER18–1639–010	Constellation Mystic Power, LLC.
E–5	ER17–998–001, EL17–61–001, EL18–91–000 (not consolidated).	DATC Path 15, LLC.
E–6	OMITTED.	
E–7	ER20–1720–001, ER20–1720–002	Southern California Edison Company.
E–8	ER20–1739–000, ER20–1739–001	American Transmission Systems, Incorporated and PJM Interconnection, L.L.C.
E–9	EL21–9–000	North Carolina Electric Membership Corporation v. Duke Energy Progress, LLC.
E–10	ER20–1237–001, ER20–1237–002	Ameren Illinois Company.
E–11	ER17–1609–003	Carroll County Energy LLC.
	ER19–1215–002	Cricket Valley Energy Center, LLC.
E–12	EL21–49–001	Hecate Energy Greene County 3 LLC v. Central Hudson Gas & Electric Corporation and New York Independent System Operator, Inc.
E–13	EL21–70–000	Luna Valley Solar I, LLC v. Pacific Gas and Electric Company and California Independent System Operator Corporation.
E–14	EL21–73–000	Edgecombe Solar Energy LLC v. Duke Energy Progress, LLC, Duke Energy Florida, LLC, and Duke Energy Carolinas, LLC.
E–15	ER21–1065–002	TransCanyon Western Development, LLC.
E–16	EL21–89–000, QF21–629–001	Hecate Energy Blair Road LLC.
E–17	IN21–9–000	Golden Spread Electric Cooperative, Inc.
	Gas	
G–1	RP15–904–003	Gas Transmission Northwest LLC.
G–2	RP21–576–001	Transcontinental Gas Pipe Line Company, LLC.
	Hydro	
H–1	P–5737–013	Santa Clara Valley Water District.
H–2	P–14867–002	Scott's Mill Hydro, LLC.
H–3	P–14869–002	RAMM Power Group, LLC.
H–4	P–2310–227	Pacific Gas and Electric Company.
	P–2784–006, P–14530–001	Nevada Irrigation District.
H–5	P–2487–048	Hydro Power, Inc. and Albany Engineering Corporation.
H–6	P–15030–000	Desert Pumped Storage, LLC.
	Certificates	
C–1	CP17–494–004	Pacific Connector Gas Pipeline, LP.
	CP17–495–004	Jordan Cove Energy Project L.P.
C–2	CP21–116–001	Gulf States Transmission LLC.
C–3	CP21–23–000	Columbia Gas Transmission, LLC.
C–4	CP17–40–010	Spire STL Pipeline LLC.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502–8400.

For a recorded message listing items struck from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed on line at the Commission's website at *https://elibrary.ferc.gov/eLibrary/search* using the eLibrary link.

The public is invited to listen to the meeting live at *http://ferc.capitolconnection.org/.* Anyone with internet access who desires to hear this event can do so by navigating to *www.ferc.gov*'s Calendar of Events and locating this event in the Calendar. The event will contain a link to its audio webcast. The Capitol Connection provides technical support for this free audio webcast. It will also offer access to this event via phone bridge for a fee. If you have any questions, visit *http://ferc.capitolconnection.org/* or contact Shirley Al-Jarani at 703–993–3104.

Dated: November 10, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–25079 Filed 11–12–21; 4:15 pm]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–193–000.
Applicants: Equitrans, L.P.
Description: Compliance filing: Compliance Filing—Order No. 587–Z to be effective 6/1/2022.
Filed Date: 11/8/21.
Accession Number: 20211108–5049.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP22–194–000.
Applicants: Rager Mountain Storage Company LLC.
Description: Compliance filing: Compliance Filing—Order No. 587–Z to be effective 6/1/2022.
Filed Date: 11/8/21.
Accession Number: 20211108–5050.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP22–195–000.
Applicants: USG Pipeline Company, LLC.
Description: Compliance filing: Order No. 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/8/21.
Accession Number: 20211108–5069.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP22–196–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Effective 11/1/2021 to be effective 11/1/2021.
Filed Date: 11/8/21.
Accession Number: 20211108–5164.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP22–197–000.
Applicants: KO Transmission Company.
Description: Compliance filing: KO—Order No. 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/8/21.
Accession Number: 20211108–5210.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP22–198–000.
Applicants: Panhandle Eastern Pipe Line Company, LP.
Description: Compliance filing: NAESB 3.2 Compliance to be effective 6/1/2022.
Filed Date: 11/9/21.
Accession Number: 20211109–5067.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP22–199–000.
Applicants: Trunkline Gas Company, LLC.
Description: Compliance filing: NAESB 3.2 Compliance to be effective 6/1/2022.
Filed Date: 11/9/21.
Accession Number: 20211109–5070.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP22–200–000.
Applicants: Rover Pipeline LLC.
Description: Compliance filing: NAESB 3.2 Compliance to be effective 6/1/2022.
Filed Date: 11/9/21.
Accession Number: 20211109–5071.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP22–201–000.
Applicants: Sea Robin Pipeline Company, LLC.
Description: Compliance filing: NAESB 3.2 Compliance to be effective 6/1/2022.
Filed Date: 11/9/21.
Accession Number: 20211109–5074.
Comment Date: 5 p.m. ET 11/22/21.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP21–1023–001.
Applicants: Pine Prairie Energy Center, LLC.
Description: Compliance filing: MBR Authority Info Notice, Compliance Dkt. No. RP21–1023–000 to be effective N/A.
Filed Date: 11/8/21.
Accession Number: 20211108–5000.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP21–1024–001
Applicants: SG Resources Mississippi, L.L.C.
Description: Compliance filing: MBR Authority Info Notice, Compliance Dkt. No. RP21–1024–000 to be effective N/A.
Filed Date: 11/8/21.
Accession Number: 20211108–5001.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP21–1025–001.
Applicants: Cadeville Gas Storage LLC.
Description: Compliance filing: MBR Authority Info Notice, Compliance Dkt. No. RP21–1025–000 to be effective N/A.
Filed Date: 11/5/21.
Accession Number: 20211105–5187.
Comment Date: 5 p.m. ET 11/17/21.

Docket Numbers: RP21–1026–001.
Applicants: Monroe Gas Storage Company, LLC.
Description: Compliance filing: MBR Authority Info Notice, Compliance Dkt. No. RP21–1026–000 to be effective N/A.
Filed Date: 11/5/21.
Accession Number: 20211105–5199.
Comment Date: 5 p.m. ET 11/17/21.

Docket Numbers: RP21–1027–001.
Applicants: Perryville Gas Storage LLC.
Description: Compliance filing: MBR Authority Info Notice, Compliance Dkt. No. RP21–1027–000 to be effective N/A.
Filed Date: 11/5/21.
Accession Number: 20211105–5202.
Comment Date: 5 p.m. ET 11/17/21.

Docket Numbers: RP21–1126–000.
Applicants: Portland Natural Gas Transmission System.
Description: Report Filing: CP20–16–000—WXP Notification of Commencement November 1, 2021 to be effective N/A.
Filed Date: 11/5/21.
Accession Number: 20211105–5108.
Comment Date: 5 p.m. ET 11/17/21.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 09, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24986 Filed 11–15–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–738–008; ER11–3097–012; ER10–1186–011; ER12–421–004; ER11–2731–004; ER10–1329–011.

Applicants: DTE Electric Company; DTE Energy Trading, Inc.; DTE Energy Supply, Inc.; DTE Garden Wind Farm, LLC; DTE Stoney Corners Wind Farm, LLC; St. Paul Cogeneration, LLC.

Description: Response to October 7, 2021 Deficiency Letter of DTE MBR Entities.

Filed Date: 11/5/21.

Accession Number: 20211105–5214.

Comment Date: 5 p.m. ET 11/26/21.

Docket Numbers: ER16–1275–003; ER16–2071–002; ER17–2342–003; ER17–2343–003; ER18–348–003; ER21–2532–001; ER21–2533–001.

Applicants: Bay Tree Lessee, LLC; Bay Tree Solar, LLC; Innovative Solar 43,

LLC; Innovative Solar 46, LLC; Shoe Creek Solar, LLC.

Description: Notice of Change in Status of Innovative Solar 46, LLC, et al.

Filed Date: 11/8/21.

Accession Number: 20211108–5244.

Comment Date: 5 p.m. ET 11/29/21.

Docket Numbers: ER20–686–005.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: Compliance filing: Compliance Filing to be effective 10/1/2021.

Filed Date: 11/9/21.

Accession Number: 20211109–5171.

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER21–2942–000.

Applicants: EnerSmart El Cajon BESS LLC.

Description: Report Filing: Supplement to Market-Based Rate Application to be effective N/A.

Filed Date: 11/8/21.

Accession Number: 20211108–5171.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER22–86–000.

Applicants: EnerSmart Chula Vista BESS LLC.

Description: Report Filing: Supplement to Market-Based Rate Application to be effective N/A.

Filed Date: 11/8/21.

Accession Number: 20211108–5176.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER22–359–000.

Applicants: Brookfield Renewable Trading and Marketing, LP.

Description: Brookfield Renewable Trading and Marketing, LP submits Petition for Limited Prospective Waiver and Request for Shortened Comment Period and Expedited Consideration.

Filed Date: 11/5/21.

Accession Number: 20211105–5219.

Comment Date: 5 p.m. ET 11/26/21.

Docket Numbers: ER22–362–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2827R7 KPP and Evergy Kansas Central Meter Agent Agreement to be effective 11/1/2021.

Filed Date: 11/9/21.

Accession Number: 20211109–5028.

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER22–363–000.

Applicants: American Electric Power Service Corporation, Appalachian Power Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: American Electric Power Service Corporation submits tariff filing per 35.13(a)(2)(iii: AEP submits one FA with City of Danville re: SA No. 2104 to be effective 1/9/2022.

Filed Date: 11/9/21.

Accession Number: 20211109–5095.

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER22–364–000.

Applicants: Southern California Edison Company.

Description: Tariff Amendment: Cancel GIA DSA Tajiguas WDT222 SA No 168 169 to be effective 1/9/2022.

Filed Date: 11/9/21.

Accession Number: 20211109–5110.

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER22–365–000.

Applicants: Georgia Power Company.

Description: § 205(d) Rate Filing: GPCo 2021 PBOP Filing to be effective 1/1/2021.

Filed Date: 11/9/21.

Accession Number: 20211109–5123.

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER22–366–000.

Applicants: Mississippi Power Company.

Description: § 205(d) Rate Filing: PBOP 2021 Filing to be effective 1/1/2021.

Filed Date: 11/9/21.

Accession Number: 20211109–5124.

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER22–367–000.

Applicants: Southern Electric Generating Company.

Description: § 205(d) Rate Filing: SEGCo 2021 PBOP Filing to be effective 1/1/2021.

Filed Date: 11/9/21.

Accession Number: 20211109–5125.

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER22–368–000.

Applicants: Alabama Power Company.

Description: Initial rate filing: Chipola River Affected System Upgrade Agreement Filing to be effective 10/18/2021.

Filed Date: 11/9/21

Accession Number: 20211109–5154

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER22–369–000.

Applicants: Georgia Power Company.

Description: Initial rate filing: Chipola River Affected System Upgrade Agreement Filing to be effective 10/18/2021.

Filed Date: 11/9/21.

Accession Number: 20211109–5155.

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER22–370–000.

Applicants: Mississippi Power Company.

Description: Initial rate filing: Chipola River Affected System Upgrade Agreement Filing to be effective 10/18/2021.

Filed Date: 11/9/21.

Accession Number: 20211109–5156.

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER22–371–000.

Applicants: Alabama Power Company.

Description: Initial rate filing: Slavic Solar Affected System Upgrade Agreement Filing to be effective 10/18/2021.

Filed Date: 11/9/21.

Accession Number: 20211109–5157.

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER22–372–000.

Applicants: Georgia Power Company.

Description: Initial rate filing: Slavic Solar Affected System Upgrade Agreement Filing to be effective 10/18/2021.

Filed Date: 11/9/21.

Accession Number: 20211109–5159.

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER22–373–000.

Applicants: Mississippi Power Company.

Description: Initial rate filing: Slavic Solar Affected System Upgrade Agreement Filing to be effective 10/18/2021.

Filed Date: 11/9/21.

Accession Number: 20211109–5160.

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER22–374–000.

Applicants: Basin Electric Power Cooperative.

Description: § 205(d) Rate Filing: Basin Electric Submission of Certificates of Concurrence to be effective 11/9/2021.

Filed Date: 11/9/21.

Accession Number: 20211109–5176.

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER22–375–000.

Applicants: Northern States Power Company, a Minnesota corporation.

Description: § 205(d) Rate Filing: 2021–11–09 Huntley-Wilmarth-OMA–658–0.0.0 to be effective 11/10/2021.

Filed Date: 11/9/21.

Accession Number: 20211109–5178.

Comment Date: 5 p.m. ET 11/30/21.

Docket Numbers: ER22–376–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Initial Filing of Rate Schedule No. 896 to be effective 11/3/2021.

Filed Date: 11/9/21.

Accession Number: 20211109–5181.

Comment Date: 5 p.m. ET 11/30/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern

time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 9, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24987 Filed 11–15–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket Nos.	File date	Presenter or requester
Prohibited:		
CP95–35–000	11–5–2021	FERC Staff. [1]
Exempt:		
1. CP15–554–000, CP15–555–000	11–2–2021	U.S. Senator Mark R. Warner.
2. CP17–458–00	11–4–2021	U.S. Representative Tom Cole.
3. P–10489–019	11–4–2021	U.S. Senator Tammy Baldwin.

[1] Telephone Memorandum dated 11/3/2021 regarding call between Commission staff and EcoEléctrica representatives.

Dated: November 9, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24988 Filed 11–15–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PL21–3–000]

Technical Conference on Greenhouse Gas Mitigation: Natural Gas Act Sections 3 and 7 Authorizations; Supplemental Notice of Technical Conference

As announced in the Notice of Technical Conference issued in this proceeding on September 16, 2021, the Federal Energy Regulatory Commission (Commission) will convene a Commission staff-led technical conference to discuss methods natural gas companies may use to mitigate the effects of direct and indirect greenhouse gas emissions resulting from Natural Gas Act sections 3 and 7 authorizations. The technical conference will be held on Friday, November 19, 2021, from approximately 9:00 a.m. to 3:30 p.m. Eastern time. The conference will be held virtually.

Attached to this Supplemental Notice is a revised agenda for the technical conference, which includes the final conference program and expected speakers. The conference will be open for the public to attend virtually. Registration is not required and there is no fee for attendance. Information on this technical conference, including a link to the public webcast, is available at *www.ferc.gov/GhG-mitigation.* The conference is also posted on the Calendar of Events on the Commission's website, *www.ferc.gov.* Transcripts will be available for a fee from Ace Reporting, (202) 347–3700.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov,* call toll-free (866) 208–3372 (voice) or (202) 208–8659 (TTY), or send a fax to (202) 208–2106 with the required accommodations.

For more information about this technical conference, please contact *GHGTechConf@ferc.gov.* For information related to logistics, please contact Sarah McKinley at *sarah.mckinley@ferc.gov* or (202) 502–8368.

Dated: November 9, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24985 Filed 11–15–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R07–RCRA–2021–0665; FRL–9126–01–R7]

Kansas: Notice of Modification to Kansas' Research, Development and Demonstration (RD&D) Permit Provisions for Municipal Solid Waste Landfills (MSWLF)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On May 10, 2016, EPA issued a revision to the regulations allowing Research, Development and Demonstration (RD&D) permits to increase the number of permit renewals allowed to six, for a total permit term of up to 21 years. On October 19, 2016, Kansas Department of Health and Environment (KDHE) submitted a notification to EPA Region 7 regarding a modification by policy to its RD&D program. EPA acknowledges receipt of Kansas' notification regarding a modification to its RD&D program, and that Kansas' notification meets the requirements set forth in the **Federal Register** document that published on May 10, 2016.

DATES: The modification to the Kansas RD&D permit program will become applicable on November 16, 2021.

FOR FURTHER INFORMATION CONTACT: Marcus G. Rivas, U.S. EPA Region 7 Land, Chemicals and Redevelopment Division; 11201 Renner Boulevard, Lenexa, Kansas 66219, (913) 551–7669, *rivas.marcus@epa.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

On March 22, 2004, EPA issued a final rule amending the Municipal Solid Waste Landfills (MSWLF) criteria in 40 CFR part 258 to allow for RD&D permits (69 FR 13242). This rule allows for variances from specified criteria for a limited period of time, to be implemented through state-issued RD&D permits. RD&D permits are available only in states with approved MSWLF permit programs that have been modified to incorporate RD&D permit authority. On May 10, 2016, the EPA issued a revision to the regulations allowing RD&D permits to increase the number of permit renewals allowed to six, for a total permit term of up to 21 years (40 CFR 258.4).

While states are not required to incorporate this new RD&D permit provision into their previous approved MSWLF program, those states interested in increasing the total length of time for which RD&D permits can be issued, from 12 years to 21 years, must provide notification to EPA in accordance with 40 CFR part 239.

On September 4, 2009, Kansas received approval of its RD&D permit program (74 FR 45769). Kansas' RD&D provisions can be found in Kansas Statutes Annotated (K.S.A.) Chapter 65—Public Health, Article 34—Solid Waste and Kansas Administrative Regulations (K.A.R.), Agency 28—Kansas Department of Health and Environment, Article 29—Solid Waste Management. On October 19, 2016, KDHE submitted a notification to EPA Region 7 of its modification of its RD&D program through policy, increasing the total length of time for which RD&D permits can be issued from 12 years to 21 years as described in the **Federal Register** document that published on May 10, 2016, (81 FR 28720) and at 40 CFR 239.12.

B. EPA Acknowledgment of Notification

In today's **Federal Register** document, EPA acknowledges receipt of the notification provided by Kansas of its modification by policy in increasing the total length of time for which RD&D permits can be issued from 12 years to 21 years, and that Kansas' notification meets the requirements set forth at 81 FR 28720 and 40 CFR 239.12.

Authority: This action is issued under the authority of section 2002, 4005 and 4010(c) of the Solid Waste Disposal Act, as amended, 40 U.S.C. 6912, 6945 and 6949(a).

Dated: November 8, 2021.

Edward H. Chu,

Acting Regional Administrator, Region 7.

[FR Doc. 2021–24947 Filed 11–15–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9259–01–OW]

Meeting of the National Drinking Water Advisory Council

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of a public meeting.

SUMMARY: The U.S. Environmental Protection Agency's (EPA) Office of Ground Water and Drinking Water is announcing a virtual meeting of the National Drinking Water Advisory Council (NDWAC or Council) as authorized under the Safe Drinking Water Act (SDWA). During this meeting the NDWAC will primarily focus discussions on developing advice and recommendations to EPA on targeted issues related to revisions to the Consumer Confidence Report rule, as required by the America's Water Infrastructure Act of 2018.

DATES: The meeting will be held on December 1, 2021, from 10:30 a.m. to 5:30 p.m., eastern time; and on December 2, 2021 from 10:00 a.m. to 5:30 p.m., eastern time.

ADDRESSES: This will be a virtual meeting. There will be no in-person gathering for this meeting. For more information about attending, providing oral statements, and accessibility for the meeting, as well as sending written comments, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Corr, NDWAC Designated Federal Officer, Office of Ground Water and Drinking Water (Mail Code 4601), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 564–3798; email address: *corr.elizabeth@epa.gov.*

SUPPLEMENTARY INFORMATION:

Attending the Meeting: The meeting will be open to the general public. The meeting agenda, including additional topics for discussion, and information on how to register for and attend the meeting online will be provided on EPA's website at *https://www.epa.gov/ndwac* prior to the meeting.

Oral Statements: EPA will allocate one hour for the public to present oral comments during the meeting. Oral statements will be limited to five minutes per person during the public comment period. It is preferred that only one person present a statement on behalf of a group or organization. Persons interested in presenting an oral statement should send an email to Elizabeth Corr, at *corr.elizabeth@epa.gov* by noon, eastern time, on November 23, 2021.

Written Statements: Any person who wishes to file a written statement can do so before or after the Council meeting. Send written statements by email to *corr.elizabeth@epa.gov* or see the **FOR FURTHER INFORMATION CONTACT** section if sending statements by mail. Written statements received by noon, eastern time, on November 23, 2021, will be distributed to all members of the Council prior to the meeting. Statements received after that time will become part of the permanent file for the meeting and will be forwarded to the Council members after conclusion of the meeting.

Accessibility: For information on access or services for individuals with disabilities, or to request

accommodations for a disability, please contact Elizabeth Corr by email at *corr.elizabeth@epa.gov,* or by phone at (202) 564–3798, preferably at least 10 days prior to the meeting to allow as much time as possible to process your request.

National Drinking Water Advisory Council: The NDWAC was created by Congress on December 16, 1974, as part of the Safe Drinking Water Act (SDWA) of 1974, Public Law 93–523, 42 U.S.C. 300j–5, and is operated in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2. The NDWAC was established to advise, consult with, and make recommendations to the EPA Administrator on matters relating to activities, functions, policies, and regulations under SDWA. General information concerning the NDWAC is available at: *https://www.epa.gov/ndwac.*

Jennifer L. McLain,

Director, Office of Ground Water and Drinking Water.

[FR Doc. 2021–24941 Filed 11–15–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9258–01–OA]

Notification of Public Meetings of the Science Advisory Board Radiation Advisory Committee Augmented for the Review of Revision 2 of the Multi-Agency Radiation Survey and Site Investigation Manual

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) Science Advisory Board (SAB) Staff Office announces two virtual public meetings of the SAB Radiation Advisory Committee (RAC) Augmented for the Review of Revision 2 of the Multi-Agency Radiation Survey and Site Investigation Manual l(MARSSIM), Revision 2 (Public Comment Draft).

DATES: The public meetings will be held on Monday December 6, 2021, and Thursday December 9, 2021. The meetings will be held from 1:00 p.m. to 5:00 p.m. (Eastern Standard Time) on both days.

ADDRESSES: The meetings will be conducted virtually. Please refer to the SAB website at *https://sab.epa.gov* for details on how to access the meetings.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wants further information concerning this notice may contact Dr. Diana Wong, Designated Federal Officer (DFO), via telephone (202) 564–2049, or email at *wong.diana-m@epa.gov.* General information about the SAB, as well as any updates concerning the meetings announced in this notice can be found on the SAB website at *https://sab.epa.gov.*

SUPPLEMENTARY INFORMATION:

Background: The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDAA) codified at 42 U.S.C. 4365, to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. Pursuant to FACA and EPA policy, notice is hereby given that the SAB MARSSIM Panel will hold two virtual public meetings to discuss its draft report regarding the draft *Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM), Revision 2 (Public Comment Draft).* The Panel will provide advice to the Administrator through the chartered SAB regarding this document.

The SAB MARSSIM Panel held a public meeting on January 11–14, 2021. The purpose of that meeting was to develop responses to the peer review charge on the agency's draft *Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM), Revision 2 (Draft for Public Comments)*). The purpose of these virtual public meetings is for the Panel to discuss these responses and draft report. The two public meetings will be conducted as one complete meeting, beginning on December 6, 2021, and if necessary, will continue on December 9, 2021.

Availability of Meeting Materials: Additional background on this SAB activity, the meeting agenda, draft report, and other materials for the meetings will be posted on the SAB website at: *https://sab.epa.gov.*

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees and panels, including scientific advisory committees, provide independent advice to the EPA. Members of the public can submit relevant comments pertaining to the meeting materials or the group conducting this SAB activity. Input from the public to the SAB will have the most impact if it consists of comments that provide specific scientific or technical information or analysis for SAB committees and panels to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should contact the DFO directly.

Oral Statements: In general, individuals or groups requesting an oral presentation on a public meeting will be limited to three minutes per speaker. Interested parties wishing to provide comments should contact Dr. Diana Wong, DFO (preferably via email), at the contact information noted above, by November 29, 2021, to be placed on the list of public speakers for the meeting.

Written Statements: Written statements will be accepted throughout the advisory process; however, for timely consideration by SAB RFT Review Panel members, statements should be received in the SAB Staff Office by November 29, 2021, for consideration at the public meeting(s). Written statements should be supplied to the DFO via email at the contact information above. Submitters are requested to provide a signed and unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its websites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB website. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact Dr. Diana Wong at *wong.diana-m@epa.gov.* To request accommodation of a disability, please contact Dr. Wong preferably at least ten days prior to the meeting, to give EPA as much time as possible to process your request.

Thomas Brennan,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2021–25003 Filed 11–15–21; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice 2021–6042]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995. EXIM's borrowers, financial institution policy holders and guaranteed lenders provide this form to U.S. exporters, who certify to the eligibility of their exports for EXIM support. For direct loans and loan guarantees, the completed form is required to be submitted at time of disbursement and held by either the guaranteed lender or EXIM. For MT insurance, the completed forms are held by the financial institution, only to be submitted to EXIM in the event of a claim filing. EXIM uses the referenced form to obtain information from exporters regarding the export transaction and content sourcing. These details are necessary to determine the value and legitimacy of EXIM financing support and claims submitted. It also provides the financial institutions a check on the export transaction's eligibility at the time it is fulfilling a financing request.

DATES: Comments must be received on or before January 18, 2022 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *www.regulations.gov* (EIB 21–02) or by email to Donna Schneider <*donna.schneider@exim.gov*>, or by mail to Donna Schneider, Export-Import Bank, 811 Vermont Ave. NW, Washington, DC 20571. The information collection tool can be reviewed at: *https://www.exim.gov/sites/default/files/pub/pending/eib21-02.pdf.*

FOR FURTHER INFORMATION CONTACT: To request additional information, please Donna Schneider <*donna.schneider@exim.gov*>, 202–565–3612.

SUPPLEMENTARY INFORMATION:

Title and Form Number: EIB 21–02 Co-financing Certificate.

OMB Number: ####–####.

Type of Review: Regular.

Need and Use: The information collected will allow EXIM to determine compliance and content for transaction requests submitted to the Export-Import Bank under its insurance, guarantee, and direct loan programs.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 25.

Estimated Time per Respondent: 30 minutes.

Annual Burden Hours: 12.5 hours.

Frequency of Reporting of Use: As required.

Government Expenses:

Reviewing time per year: 2.1 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $89.25 (time * wages).

Benefits and Overhead: 20%.

Total Government Cost: $107.10.

Bassam Doughman,

IT Specialist.

[FR Doc. 2021–24960 Filed 11–15–21; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice 2021–6044]

Agency Information Collection Activities: Final Collection; Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as a part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995. The Multi-Buyer Policy: Reasonable Spread of Risk (RSOR) Exclusions Worksheet will be used by external customers, current policyholders and portfolio managers to determine eligibility of Export-Import Bank support under the RSOR Policy. Program changes that were made in 2017 have resulted in revitalized demand of the RSOR product in the marketplace. This form will be available on EXIM's website and will standardize the collection of required information into a user friendly format that can be submitted electronically via email or as an attachment to an EXIM Online application.

DATES: Comments should be received on or before January 18, 2022 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *www.regulations.gov* (EIB 18–01) or by email to Cristina Conti <*cristina.conti@exim.gov*>, or by mail to Cristina Conti, Export-Import Bank of the United States, 811 Vermont Ave. NW, Washington, DC 20571.

The form can be viewed at: *https://www.exim.gov/sites/default/files/pub/pending/eib18-01.pdf.*

FOR FURTHER INFORMATION CONTACT: To request additional information, please Cristina Conti <*cristina.conti@exim.gov*>, 202–565–3804.

SUPPLEMENTARY INFORMATION: *Titles and Form Number:* EIB18–01 Multi-Buyer Policy: Reasonable Spread of Risk (RSOR) Exclusions Worksheet.

OMB Number: XXXX–XXXX.

Type of Review: New.

Need and Use: The Multi-Buyer Policy: Reasonable Spread of Risk (RSOR) Exclusions Worksheet will be used by external customers, current policyholders and portfolio managers to determine eligibility of Export-Import Bank support under the Reasonable Spread of Risk Policy.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 60.

Estimated Time per Respondent: 15 minutes.

Annual Burden Hours: 15 hours.

Frequency of Reporting or Use: As needed.

Government Expenses:

Reviewing Time per Year: 60 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $2,550 (time * wages).

Benefits and Overhead: 20%.

Total Government Cost: $3,060.

Bassam Doughman,

IT Specialist.

[FR Doc. 2021–24979 Filed 11–15–21; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2021–3041]

Privacy Act of 1974; System of Records

AGENCY: Export-Import Bank of the United States.

ACTION: Notice of new system of records.

SUMMARY: Pursuant to the Privacy Act of 1974 the Export-Import Bank of the United States (EXIM) is proposing a new system of records notice (SORN). EXIM is proposing EXIM 21–02 Reasonable Accommodation Records. This new SORN will include the authorities for maintenance of the system, the purposes of the system, the categories of individuals covered by the system, the

record source categories, and the records contained in the system, to include records of requests for accommodation based on physical and mental disabilities and sincerely held religious beliefs, practices, or observances.

DATES: The system of records described herein will become effective December 16, 2021.

ADDRESSES: You may submit written comments to EXIM by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the website instructions for submitting comments.
- *Mail or Hand Delivery:* Office of Information and Privacy, Export-Import Bank of the United States, 811 Vermont Avenue NW, Washington, DC 20571.

Commenters are strongly encouraged to submit public comments electronically. EXIM expects to have limited personnel available to process public comments that are submitted on paper through mail. Until further notice, any comments submitted on paper will be considered to the extent practicable.

All submissions must include the agency's name (Export-Import Bank of the United States, or EXIM) and reference this notice. Comments received will be posted without change to EXIM's website, *http://www.exim.gov,* including any personal information provided. Do not submit comments that include any personally identifiable information or confidential business information. Copies of comments may also be obtained by writing to Nakia Burton, Export-Import Bank of the United States, 811 Vermont Avenue NW, Washington, DC 20571.

FOR FURTHER INFORMATION CONTACT: Howard Spira, Chief Privacy Officer, Export-Import Bank of the United States, Office of Information and Privacy, 811 Vermont Avenue NW, Washington, DC 20571, 202–565–3844. For access to any of the EXIM's systems of records, contact Bassam Doughman, Records Management Officer, Office of Information and Privacy, 811 Vermont Avenue NW, Washington, DC 20571, or by calling 202–565–3168, or go to Privacy Act System of Records Notice (*exim.gov*).

SUPPLEMENTARY INFORMATION: EXIM is proposing to include the authorities for maintenance of the system, purposes of the system, the categories of records contained in the system, the categories of individuals covered by the system, the record source categories, a citation in the Routine Uses section, a citation in the Record Access Procedures section, and a citation in the Contesting Records Procedures section of EXIM—21–03—Reasonable Accommodation Records.

EXIM is including the Authority for Maintenance of the System by including citations to ''42 U.S.C. 2000e *et seq.,* 42 U.S.C. 2000bb *et seq.*'' and including Chapter 21 from Title 42 of the United States Code and Parts 1605 and 1614 from Title 29 of the Code of Federal Regulations. EXIM is including the purposes of the system that allows EXIM to maintain records on individuals who requested or received reasonable accommodation by EXIM because of religious beliefs. EXIM is describing the Categories of Records Contained in the System to include information concerning the individual's physical and/or mental disabilities and/or religious belief. EXIM is defining the Categories of Individuals Covered by the System by including the words ''physical and/or mental disabilities, and/or religious belief, practice or observance'' to include accommodation requests based on physical and/or mental disabilities and/or sincerely held religious beliefs and including ''equal employment opportunity professionals'' to Record Source Categories. EXIM is also including the citation to 29 CFR 4902.5 to the Contesting Records Procedures section.

A report will be sent to Congress and the Office of Management and Budget for their evaluation.

For the convenience of the public, EXIM's new system of records is published in full below.

Issued in Washington, DC.

Howard Spira,

Senior Vice President, Office of Information and Privacy, Export-Import Bank of the United States.

SYSTEM NAME AND NUMBER:

EXIM—XX: Reasonable Accommodation Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Export-Import Bank of the United States, 811 Vermont Avenue NW, Washington, DC 20571. (Records may be kept at an additional location as backup for continuity of operations.)

SYSTEM MANAGER(S) AND ADDRESS:

Reasonable Accommodations Coordinator, Office of Human Capital, EXIM, 811 Vermont Avenue NW, Washington, DC 20571.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

29 U.S.C. 1302; 44 U.S.C. 3101; 5 U.S.C. 301; 29 U.S.C. 701 *et seq.;* 29 U.S.C. 791; 42 U.S.C. 12101 *et seq.;* 42 U.S.C. 2000e *et seq.;* 42 U.S.C. 2000bb; 42 U.S.C. Ch. 21, 126; 29 CFR parts 1605, 1614, 1630; Executive Order 13164 (July 26, 2000); and Executive Order 13548 (July 26, 2010).

PURPOSE(S) OF THE SYSTEM:

The purposes of this system are: (1) To allow EXIM to collect and maintain records on applicants, current, and former employees and other individuals who participate in EXIM programs or activities with physical and/or mental disabilities, and/or sincerely held religious beliefs, practices, or observances who request and/or receive reasonable accommodation by EXIM; (2) to track and report the processing of requests for reasonable accommodation EXIM-wide to comply with applicable law and regulations; and (3) to maintain the confidentiality of medical and/or religious information submitted by or on behalf of applicants or employees requesting reasonable accommodation.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants, current, and former employees of EXIM and visitors to Federal buildings who request and/or receive a reasonable accommodation or appropriate modifications from EXIM for a physical and/or mental disability, and/or religious belief, practice, or observance; Authorized individuals or representatives (*e.g.,* family members, union representatives, or attorneys) who submit a request for a reasonable accommodation on behalf of an applicant, current, or former employee.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name and employment information of applicants and employees requesting and granted or denied an accommodation; the requester's name and contact information (if different than the applicant or employee who needs an accommodation); date request was initiated; information concerning the nature of the disability or religious belief, practice, or observance and the need for accommodation, including appropriate medical or other documentation; occupational series; pay grade; requester's statement of a sincerely held religious belief and any additional information provided concerning that religious belief and the need for an accommodation to exercise that belief; essential functions of the position; details of the accommodation request, such as: Type of accommodation requested, how the requested accommodation would assist in job or allow job performance while accommodating the disability or

religious belief, practice, or observance, the sources of technical assistance consulted in trying to identify alternative reasonable accommodation, any additional information provided by the requester relating to the processing of the request, whether the request was approved or denied, whether the accommodation was approved for a trial period; and, documentation between the applicant and EXIM, employee and his/her supervisor(s) regarding the accommodation.

RECORD SOURCE CATEGORIES:

Subject individuals or individual making the request (if different than the subject individuals); medical and equal employment opportunity professionals directly or indirectly from an individual's medical provider or another medical professional who evaluates the request, directly or indirectly from an individual's religious or spiritual advisors or institutions; and the subject individuals' supervisor(s).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside EXIM as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

a. To the Department of Justice, including Offices of the U.S. Attorneys; another Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body; another party in litigation before a court, adjudicative, or administrative body; or to a court, adjudicative, or administrative body. Such disclosure is permitted only when it is relevant or necessary to the litigation or proceeding, and one of the following is a party to the litigation or has an interest in such litigation:

(1) EXIM, or any component thereof;

(2) Any employee or former employee of EXIM in his or her official capacity;

(3) Any employee or former employee of EXIM in his or her capacity where the Department of Justice or EXIM has agreed to represent the employee;

(4) The United States, a Federal agency, or another party in litigation before a court, adjudicative, or administrative body, upon EXIM General Counsel's approval, pursuant to 5 CFR part 295 or otherwise.

b. To the appropriate Federal, State, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates or is relevant to a violation or potential violation of civil or criminal law or regulation.

c. To a member of Congress from the record of an individual in response to an inquiry made at the request of the individual to whom the record pertains.

d. To the National Archives and Records Administration (NARA) for records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

e. To appropriate agencies, entities, and persons when (1) EXIM suspects or has confirmed that there has been a breach of the system of records; (2) EXIM has determined that as a result of the suspected or confirmed breach, there is a risk of harm to individuals, EXIM (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 EXIM's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

f. To another Federal agency or Federal entity, when EXIM 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.

g. To contractors, grantees, experts, consultants, or volunteers performing or working on a contract, service, grant, cooperative agreement, or other assignment for EXIM when EXIM determines that it is necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to EXIM employees.

h. To another federal agency or commission with responsibility for labor or employment relations or other issues, including equal employment opportunity and reasonable accommodation issues, when that agency or commission has jurisdiction over reasonable accommodation.

i. To an authorized appeal grievance examiner, formal complaints examiner, administrative judge, equal employment opportunity investigator, arbitrator, or other duly authorized official engages in investigation or settlement of a grievance, complaint, or appeal filed by an individual who requested a reasonable accommodation or other appropriate modification.

j. To another Federal agency, including but not limited to the Equal Employment Opportunity Commission and the Office of Special Counsel to obtain advice regarding statutory, regulatory, policy, and other requirements related to reasonable accommodation.

k. To a Federal agency or entity authorized to procure assistive technologies and services in response to a request for reasonable accommodation.

l. To first aid and safety personnel if the individual's medical condition requires emergency treatment.

m. To another Federal agency or oversight body charged with evaluating EXIM's compliance with the laws, regulations, and policies governing reasonable accommodation requests.

n. To another Federal agency pursuant to a written agreement with EXIM to provide services (such as medical evaluations), when necessary, in support of reasonable accommodation decisions.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained manually in paper and/or electronic form (including computer databases or discs). Records may also be maintained on back-up tapes, or on an EXIM or a contractor-hosted network.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by any one or more of the following: Applicant or employee name or assigned case number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained and destroyed in accordance with the National Archives and Record Administration's (NARA) Basic Laws and Authorities (44 U.S.C. 3301, *et seq.*) or a EXIM records disposition schedule approved by NARA. Records existing on paper are destroyed beyond recognition.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

EXIM has established security and privacy protocols that meet the required security and privacy standards issued by the National Institute of Standards and Technology (NIST). Records are maintained in a secure, password

protected electronic system that utilizes security hardware and software to include multiple firewalls, active intruder detection, and role-based access controls. EXIM has adopted appropriate administrative, technical, and physical controls in accordance with EXIM's security program to protect the confidentiality, integrity, and availability of the information, and to ensure that records are not disclosed to or accessed by unauthorized individuals.

Electronic records are stored on computer networks, which may include cloud-based systems, and protected by controlled access with Personal Identity Verification (PIV) cards, assigning user accounts to individuals needing access to the records and by passwords set by authorized users that must be changed periodically.

RECORD ACCESS PROCEDURES:

Individuals, or third parties with written authorization from the individual, wishing to request access to their records in accordance with 12 CFR 404.14 or to amend records pertaining to themselves in accordance with 2912 CFR 404.18, should submit a written request to the Freedom of Information and Privacy Act Office, EXIM, 811 Vermont Avenue NW, Washington, DC 20571, providing their name, address, date of birth, and verification of their identity in accordance with 12 § 1404.14(d & e).

CONTESTING RECORD PROCEDURES:

Individuals, or third parties with written authorization from the individual, wishing to amend their records, in accordance with 12 CFR 1404.18 must submit a written request identifying the information they wish to correct in their file, in addition to following the requirements of the Record Access Procedure above.

NOTIFICATION PROCEDURES:

Individuals, or third parties with written authorization from the individual, wishing to learn whether this system of records contains information about them should submit a written request to the Freedom of Information and Privacy Act Office, EXIM, 811 Vermont Avenue NW, Washington, DC 20571, providing their name, address, date of birth, and verification of their identity in accordance with 29 CFR 4902.3(c).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Bassam Doughman,

IT Specialist.

[FR Doc. 2021–24924 Filed 11–15–21; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2021–6043]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995. EXIM's borrowers, financial institution policy holders and guaranteed lenders provide this form to U.S. exporters, who certify to the eligibility of their exports for EXIM support. For direct loans and loan guarantees, the completed form is required to be submitted at time of disbursement and held by either the guaranteed lender or EXIM. For MT insurance, the completed forms are held by the financial institution, only to be submitted to EXIM in the event of a claim filing. EXIM uses the referenced form to obtain information from exporters regarding the export transaction and content sourcing. These details are necessary to determine the value and legitimacy of EXIM financing support and claims submitted. It also provides the financial institutions a check on the export transaction's eligibility at the time it is fulfilling a financing request.

DATES: Comments must be received on or before January 18, 2022 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *www.regulations.gov* (EIB 11–05) or by email to Donna Schneider <*donna.schneider@exim.gov*>, or by mail to Donna Schneider, Export-Import Bank, 811 Vermont Ave. NW, Washington, DC 20571. The information collection tool can be reviewed at: *https://www.exim.gov/sites/default/files/pub/pending/eib11-05.pdf.*

FOR FURTHER INFORMATION CONTACT: To request additional information, please Donna Schneider *donna.schneider@exim.gov,* 202–565–3612.

SUPPLEMENTARY INFORMATION:

Title and Form Number: EIB 11–05 Exporter's Certificate for Loan Guarantee & MT Insurance Programs.

OMB Number: 3048–0043.

Type of Review: Regular.

Need and Use: The information collected will allow EXIM to determine compliance and content for transaction requests submitted to the Export-Import Bank under its insurance, guarantee, and direct loan programs.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 2,000.

Estimated Time per Respondent: 30 minutes.

Annual Burden Hours: 1,000 hours.

Frequency of Reporting of Use: As required.

Government Expenses:

Reviewing Time per Year: 167 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $7,097.50 (time * wages).

Benefits and Overhead: 20%.

Total Government Cost: $8,517.

Bassam Doughman,

IT Specialist.

[FR Doc. 2021–24968 Filed 11–15–21; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1223; FR ID 56713]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

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. 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.

SUPPLEMENTARY INFORMATION:

Title: Payment Instructions from the Eligible Entity Seeking Reimbursement from the TV Broadcaster Relocation Fund.

Form Number: FCC Form 1876.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, Not-for-profit institutions and State, Local or Tribal Government.

Number of Respondents and Responses: 350 respondents; 350 responses.

Estimated Time per Response: 5 hours.

Frequency of Response: One-time reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Middle Class Tax Relief and Job Creation Act of 2012, Public Law 112–96 (Spectrum Act) section 6403(a)(1)and Repack Airwaves Yielding Better Access for Users of Modern Services Act of 2018, Public Law 115–141, Div. P, (RAY BAUM'S Act) section 1452.

Total Annual Burden: 1,750 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No Impact(s).

Nature and Extent of Confidentiality: The information collection includes information identifying bank accounts and providing account and routing numbers to access those accounts. FCC considers that information to be records not routinely available for public inspection under 47 CFR 0.457, and exempt from disclosure under FOIA exemption 4 (5 U.S.C. 552(b)(4)).

Needs and Uses: The Commission is requesting Office of Management and Budget (OMB) approval for a three-year extension of this information collection.

The Spectrum Act requires the Commission to reimburse broadcast television licensees for costs ''reasonably incurred'' in relocating to new channels assigned in the repacking process and Multichannel Video Programming Distributors (MVPDs) for costs reasonably incurred in order to continue to carry the signals of stations relocating to new channels as a result of the repacking process or a winning reverse auction bid.[1]

The Commission decided through notice-and-comment rulemaking that it will issue all eligible broadcasters and MVPDs an initial allocation of funds based on estimated costs, which will be available for draw down (from individual accounts in the U.S. Treasury) as the entities incur expenses, followed by a subsequent allocation to the extent necessary. The reason for allowing eligible entities to draw down funds as they incur expenses is to reduce the chance that entities will be unable to finance necessary relocation changes.[2]

The information collection for which we are requesting approval is necessary for eligible entities to instruct the Commission on how to pay the amounts the entities draw down, and for the entities to make certifications that reduce the risk of waste, fraud, abuse and improper payments.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–24912 Filed 11–15–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1183; FR ID 52700]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, 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. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it can further reduce the information collection burden for small business concerns with fewer than 25 employees.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before December 16, 2021.

ADDRESSES: Comments should be sent 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. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) 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 OMB control number.

As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the

[1] Middle Class Tax Relief and Job Creation Act of 2012, Public Law 112–96 (Spectrum Act) § 6403(b)(4)(A)(i), (ii).

[2] Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions, GN Docket No. 12–268, Report and Order, 29 FCC Rcd 6567 (2014) (''Incentive Auction R&O'') at 609.

following information collection. Comments are requested concerning: (a) 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; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) 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. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–1183.

Title: Establishment of a Public Safety Answering Point Do-Not-Call Registry, CG Docket No. 12–129.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Federal Government; Not-for-profit institutions; State Local or Tribal Government.

Number of Respondents and Responses: 106,500 respondents; 1,446,333 responses.

Estimated Time per Response: 30 minutes (.50 hours) to 1 hour.

Frequency of Response: Recordkeeping requirement; Annually, monthly, on occasion and one-time reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for the information collection requirements is found in the Middle Class Tax Relief and Job Creation Act of 2012, Public Law 112–96, February 22, 2012.

Total Annual Burden: 792,667 hours.

Total Annual Cost: None.

Needs and Uses: The rules adopted herein establish recordkeeping requirements for a large variety of entities, including small business entities. First, each Public Safety Answering Point (PSAP) may designate a representative who shall be required to file a certification with the administrator of the PSAP registry that they are authorized to place numbers onto that registry. The designated PSAP representative shall provide contact information including the PSAP represented, name, title, address, telephone number and email address. Verified PSAPs shall be permitted to upload to the registry any PSAP telephone associated with the provision of emergency services or communications with other public safety agencies. On an annual basis designated PSAP representatives shall access the registry, review their numbers and remove any ineligible numbers from the registry. Second, an operator of automatic dialing equipment (OADE) is prohibited from contacting any number on the PSAP registry. Each OADE must register for access to the PSAP registry by providing contact information which includes name, business address, contact person, telephone number, email, and all outbound telephone numbers used to place autodialed calls. All such contact information must be updated within 30 days of any change. In addition, the OADE must certify that it is accessing the registry solely to prevent autodialed calls to numbers on the registry. An OADE must access and employ a version of the PSAP registry obtained from the registry administrator no more than 31 days prior to the date any call is made, and maintain record documenting this process. No person or entity may sell, rent, lease, purchase, share, or use the PSAP registry for any purpose expect to comply with our rules prohibiting contact with numbers on the registry.

Federal Communications Commission.

Marlene Dortch,

Secretary,Office of the Secretary.

[FR Doc. 2021–24914 Filed 11–15–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[IB Docket No. 16–185; DA 21–1398; FRS 57855]

Informal Working Group-1, Informal Working Group-2, Informal Working Group-3, and Informal Working Group-4 of the World Radiocommunication Conference Advisory Committee Schedule Their Meetings

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This notice advises interested persons that Informal Working Group 1 (IWG–1), Informal Working Group 2 (IWG–2,) Informal Working Group 3 (IWG–3, and Informal Working Group 4 (IWG–4) of the 2023 World Radiocommunication Conference Advisory Committee (WRC–23 Advisory Committee) have scheduled meetings as set forth below. The meetings are open to the public.

DATES: IWG–3: Tuesday, December 14, 2021 (11:00 a.m.–12:30 p.m. EDT); IWG–4: Tuesday, December 14, 2021 (1:00 p.m.–2:30 p.m. EDT); IWG–1, Wednesday, December 15, 2021 (10:30 a.m.–12:00 p.m. EDT); IWG–2, Wednesday, December 15, 2021 (12:00 p.m.–1:00 p.m. EDT); IWG–3: Thursday, January 6, 2022 (11:00 a.m.–1:00 p.m. EDT); IWG–4, Thursday, January 6, 2022 (1:30 p.m.–3:00 p.m. EDT); IWG–1, Wednesday, January 12, 2022 (10:00 a.m.–12:00 p.m. EDT); IWG–2, Wednesday, Wednesday, January 12, 2022 (1:00 p.m.–3:00 p.m. EDT); IWG–3: Tuesday, January 18, 2022 (11:00 a.m.–1:00 p.m. EDT); IWG–4: Tuesday, January 18, 2022 (1:30 p.m.–3:00 p.m. EDT); IWG–2, Wednesday, January 19, 2022 (11:00 a.m.–12:00 p.m. EDT); IWG–1, Wednesday, January 19, 2022 1:00 p.m.–3:00 p.m. (1:00 p.m.–3:00 p.m. EDT).

ADDRESSES: The meetings will be held virtually.

FOR FURTHER INFORMATION CONTACT: Dante Ibarra, Designated Federal Official, World Radiocommunication Conference Advisory Committee, FCC International Bureau, Global Strategy and Negotiation Division, at *Dante.Ibarra@fcc.gov,* (202)-418–0610 or *WRC-23@fcc.gov.*

SUPPLEMENTARY INFORMATION: The FCC established the Advisory Committee to provide advice, technical support and recommendations relating to the preparation of United States proposals and positions for the 2023 World Radiocommunication Conference (WRC–23).

In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, this notice advises interested persons of the IWG–1, IWG–2, IWG–3 and IWG–4 of the WRC–23 Advisory Committee scheduled meetings. The Commission's WRC–23 website (*www.fcc.gov/wrc-23*) contains the latest information on all scheduled meetings, meeting agendas, and WRC–23 Advisory Committee matters.

Below is additional IWG meeting information:

WRC–23 Advisory Committee

Schedule of Meetings of Informal Working Groups 1, 2, 3 and 4

Informal Working Group 1: Maritime, Aeronautical and Radar Services

Chair—Damon Ladson, *dladson@hwglaw.com,* telephone: (202) 730–1315

Vice Chair—Kim Kolb, *kim.l.kolb@boeing.com,* telephone: (703) 465–3373

FCC Representatives: Louis Bell, *louis.bell@fcc.gov,* telephone: (202) 418–1641; Gregory Baker, *Gregory.baker@fcc.gov,* telephone: (202) 418–0611

IWG–1—Meetings

IWG–1 Meeting Date: Wednesday, December 15, 2021

Time: 10:30 a.m.–12:00 p.m.

Join ZoomGov Meeting: https://fcc-gov.zoomgov.com/j/1617778405?pwd=dC83a2FoUXBERnEvYVFJeXFndStnQT09
Meeting ID: 161 777 8405
Passcode: 185226
One tap mobile:
+16692545252,,1617778405#,,,,*185226# US (San Jose)
+16468287666,,1617778405#,,,,*185226# US (New York)
Dial by your location:
+1 669 254 5252 U.S. (San Jose)
+1 646 828 7666 U.S. (New York)
+1 551 285 1373 U.S.
Meeting ID: 161 777 8405
Passcode: 185226
Find your local number: https://fcc-gov.zoomgov.com/u/adyt3qbEnl

IWG–1 Meeting Date: Wednesday, January 12, 2022

Time: 10:00 a.m.–12:00 p.m.

Join ZoomGov Meeting: https://fcc-gov.zoomgov.com/j/1617137240?pwd=SndFOGU4MFduREJ4ZFFabWhQbXJOQT09
Meeting ID: 161 713 7240
Passcode: 812256
One tap mobile:
+16692545252,,1617137240#,,,,*812256# U.S. (San Jose)
+16468287666,,1617137240#,,,,*812256# U.S. (New York)
Dial by your location:
+1 669 254 5252 U.S. (San Jose)
+1 646 828 7666 U.S. (New York)
+1 551 285 1373 U.S.
Meeting ID: 161 713 7240
Passcode: 812256
Find your local number: https://fcc-gov.zoomgov.com/u/aeyNT7Nwcg

IWG–1 Meeting Date: Wednesday, January 19, 2022

Time: 1:00 p.m.–3:00 p.m.

Join ZoomGov Meeting: https://fcc-gov.zoomgov.com/j/1609602718?pwd=UnQ5Qy9HT1RzcFQ2QlJvN0w5Sjl4dz09
Meeting ID: 160 960 2718
Passcode: 613945
One tap mobile:
+16692545252,,1609602718#,,,,*613945# U.S. (San Jose)
+16468287666,,1609602718#,,,,*613945# U.S. (New York)
Dial by your location:
+1 669 254 5252 U.S. (San Jose)
+1 646 828 7666 U.S. (New York)
+1 551 285 1373 U.S.
Meeting ID: 160 960 2718
Passcode: 613945
Find your local number: https://fcc-gov.zoomgov.com/u/aHL4LYTaE

Informal Working Group 2: Terrestrial Services

Chair—Jayne Stancavage, *Jayne.Stancavage@intel.com,* telephone: (408) 887–3186
Vice Chair—Jennifer Oberhausen, *joberhausen@ctia.org,* telephone: (202) 736–3235
FCC Representatives: Louis Bell, *louis.bell@fcc.gov,* telephone: (202) 418–1641; Dante Ibarra, *dante.ibarra@fcc.gov,* telephone: (202) 418–0610

IWG–2—Meetings

IWG–2 Meeting Date: Wednesday, December 15, 2021

Time: 12:00 p.m.–1:00 p.m.

Join ZoomGov Meeting: https://fcc-gov.zoomgov.com/j/1616596760?pwd=TTk3SWFqVHFXb3BKampIS2o4QnM4UT09
Meeting ID: 161 659 6760
Passcode: 804178
One tap mobile:
+16692545252,,1616596760#,,,,*804178# U.S. (San Jose)
+16468287666,,1616596760#,,,,*804178# U.S. (New York)
Dial by your location:
+1 669 254 5252 U.S. (San Jose)
+1 646 828 7666 U.S. (New York)
+1 551 285 1373 U.S.
Meeting ID: 161 659 6760
Passcode: 804178
Find your local number: https://fcc-gov.zoomgov.com/u/ad56NHDwcs

IWG–2 Meeting Date: Wednesday, January 12, 2022

Time: 1:00 p.m.–3:00 p.m.

Join ZoomGov Meeting: https://fcc-gov.zoomgov.com/j/1609999223?pwd=RXFFd3JMM2JqdGhVL1ZWWXNjeHowZz09
Meeting ID: 160 999 9223
Passcode: 600759
One tap mobile:
+16692545252,,1609999223#,,,,*600759# U.S. (San Jose)
+16468287666,,1609999223#,,,,*600759# U.S. (New York)
Dial by your location:
+1 669 254 5252 U.S. (San Jose)
+1 646 828 7666 U.S. (New York)
+1 551 285 1373 U.S.
Meeting ID: 160 999 9223
Passcode: 600759
Find your local number: https://fcc-gov.zoomgov.com/u/abhw9i3OfL

IWG–2 Meeting Date: Wednesday, January 19, 2022

Time: 11:00 a.m.–12:00 p.m.

Join ZoomGov Meeting: https://fcc-gov.zoomgov.com/j/1600848119?pwd=M3EvNUdqdFhQTGpXUnZTR0F0SDdpZz09
Meeting ID: 160 084 8119
Passcode: 413464
One tap mobile:
+16692545252,,1600848119#,,,,*413464# U.S. (San Jose)
+16468287666,,1600848119#,,,,*413464# U.S. (New York)
Dial by your location:
+1 669 254 5252 U.S. (San Jose)
+1 646 828 7666 U.S. (New York)
+1 551 285 1373 U.S.
Meeting ID: 160 084 8119
Passcode: 413464
Find your local number: https://fcc-gov.zoomgov.com/u/acqUlRpYXb

Informal Working Group 3: Space Services

Chair—Zachary Rosenbaum, *zachary.rosenbaum@ses.com,* telephone: (814) 233–7373
Vice Chair—Vacant
FCC Representatives: Clay DeCell, *clay.decell@fcc.gov,* telephone: (202) 418–0803; Kathyrn Medley, *kathyrn.medley@fcc.gov,* telephone: (202) 418–1211; Eric Grodsky, *eric.grodsky@fcc.gov,* telephone: (202) 418–0563; Dante Ibarra, *dante.ibarra@fcc.gov,* telephone: (202) 418–0610

IWG–3—Meeting

IWG–3 Meeting Date: Tuesday, December 14, 2021

Time: 11:00 a.m.–12:30 p.m.

Join ZoomGov Meeting: https://fcc-gov.zoomgov.com/j/1618565124?pwd=NWpIL0ZZSFB3Q0tzOEN1MS8zcFRpQT09
Meeting ID: 161 856 5124
Passcode: 262824
One tap mobile:
+16692545252,,1618565124#,,,,*262824# U.S. (San Jose)
+16468287666,,1618565124#,,,,*262824# U.S. (New York)
Dial by your location:
+1 669 254 5252 U.S. (San Jose)
+1 646 828 7666 U.S. (New York)
+1 551 285 1373 U.S.
Meeting ID: 161 856 5124
Passcode: 262824
Find your local number: https://fcc-gov.zoomgov.com/u/ad3N13PmvZ

IWG–3 Meeting Date: Thursday, January 6, 2022

Time: 11:00 a.m.–1:00 p.m.

Join ZoomGov Meeting: https://fcc-gov.zoomgov.com/j/1618051603?pwd=Y2xDdFRmaU4ycG1idUl6eHl4ellqQT09
Meeting ID: 161 805 1603
Passcode: 959484
One tap mobile:
+16692545252,,1618051603#,,,,*959484# U.S. (San Jose)
+16468287666,,1618051603#,,,,*959484# U.S. (New York)
Dial by your location:
+1 669 254 5252 U.S. (San Jose)
+1 646 828 7666 U.S. (New York)
+1 551 285 1373 U.S.
Meeting ID: 161 805 1603
Passcode: 959484
Find your local number: https://fcc-gov.zoomgov.com/u/abtCQiKA73

IWG–3 Meeting Date: Tuesday, January 18, 2022

Time: 11:00 a.m.–1:00 p.m.

Join ZoomGov Meeting: https://fcc-gov.zoomgov.com/j/1619422140?pwd=V0c1ZXlPTWpWbVNQNUdzUytxL1lGdz09
Meeting ID: 161 942 2140
Passcode: 248652
One tap mobile:
+16692545252,,1619422140#,,,,*248652# U.S. (San Jose)
+16468287666,,1619422140#,,,,*248652# U.S. (New York)
Dial by your location:
+1 669 254 5252 U.S. (San Jose)
+1 646 828 7666 U.S. (New York)
+1 551 285 1373 U.S.
Meeting ID: 161 942 2140
Passcode: 248652
Find your local number: https://fcc-gov.zoomgov.com/u/asiZRIBVs

Informal Working Group 4: Regulatory Issues

Chair—David Goldman, *david.goldman@spacex.com,* telephone: (202) 649–2641
Vice Chair—Giselle Creeser, *giselle.creeser@intelsat.com,* telephone: (703) 559–7851
FCC Representatives: Dante Ibarra, *dante.ibarra@fcc.gov,* telephone: (202) 418–0610; Clay DeCell, *clay.decell@fcc.gov,* telephone: (202) 418–0803

IWG–4—Meetings

IWG–4 Meeting Date: Tuesday, December 14, 2021

Time:1:00 p.m.–2:30 p.m.

Join ZoomGov Meeting: https://fcc-gov.zoomgov.com/j/1611531963?pwd=Unh5OW9PU0pzOFlUdnRKb0NQLzAzQT09
Meeting ID: 161 153 1963
Passcode: 231175
One tap mobile:
+16692545252,,1611531963#,,,,*231175# U.S. (San Jose)
+16468287666,,1611531963#,,,,*231175# U.S. (New York)
Dial by your location:
+1 669 254 5252 U.S. (San Jose)
+1 646 828 7666 U.S. (New York)
+1 551 285 1373 U.S.
Meeting ID: 161 153 1963
Passcode: 231175
Find your local number: https://fcc-gov.zoomgov.com/u/auIC4KVBe

IWG–4 Meeting Date: Thursday, January 6, 2022

Time: 1:30 p.m.–3:00 p.m.

Join ZoomGov Meeting: https://fcc-gov.zoomgov.com/j/1612806478?pwd=RDRiM3JkbDl4ZXdSNjVWMXN2U25sQT09
Meeting ID: 161 280 6478
Passcode: 991779
One tap mobile:
+16692545252,,1612806478#,,,,*991779# U.S. (San Jose)
+16468287666,,1612806478#,,,,*991779# U.S. (New York)
Dial by your location:
+1 669 254 5252 U.S. (San Jose)
+1 646 828 7666 U.S. (New York)
+1 551 285 1373 U.S.
Meeting ID: 161 280 6478
Passcode: 991779
Find your local number: https://fcc-gov.zoomgov.com/u/acRbViq7FQ

IWG–4 Meeting Date: Tuesday, January 18, 2022

Time: 1:30 p.m.–3:00 p.m.

Join ZoomGov Meeting:https://fcc-gov.zoomgov.com/j/1604198545?pwd=aGJVcEJ1UEpLWm1NTms5UExqcnlsUT09
Meeting ID: 160 419 8545
Passcode: 236341
One tap mobile:
+16692545252,,1604198545#,,,,*236341# U.S. (San Jose)
+16468287666,,1604198545#,,,,*236341# U.S. (New York)
Dial by your location:
+1 669 254 5252 U.S. (San Jose)
+1 646 828 7666 U.S. (New York)
+1 551 285 1373 U.S.
Meeting ID: 160 419 8545
Passcode: 236341
Find your local number: https://fcc-gov.zoomgov.com/u/ad242rsX3E

Federal Communications Commission.

Troy Tanner,

Deputy Chief, International Bureau.

[FR Doc. 2021–24999 Filed 11–15–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Privacy Act of 1974; System of Records

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of New System of Records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the FDIC is establishing FDIC–036 Ensuring Workplace Health and Safety in Response to a Public Health Emergency. This system of records maintains information collected in response to a public health emergency, such as a pandemic or epidemic, from FDIC personnel (including political appointees, onboarding employees, employees, detailees, contractors, consultants, interns, and volunteers), and visitors to FDIC facilities.

DATES: This action will become effective on November 16, 2021 The routine uses in this action will become effective on December 16, 2021 unless the FDIC makes changes based on comments received. Written comments should be submitted on or before December 16, 2021.

ADDRESSES: Interested parties are invited to submit written comments identified by Privacy Act Systems of Records by any of the following methods:

- *Federal eRulemaking Portal: http://regulations.gov.* Follow the instructions for submitting comments.
- *Agency website: https://www.fdic.gov/resources/regulations/federal-register-publications/.* Follow the instructions for submitting comments on the FDIC website.
- *Email: Comments@fdic.gov.*
- *Mail:* Shannon Dahn, Chief, Privacy Program, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street NW building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Shannon Dahn, Chief, Privacy Program, 703–516–5500, *privacy@fdic.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Privacy Act, 5 U.S.C. 552a, FDIC is establishing a new system of records, FDIC–036 Ensuring Workplace Health and Safety in Response to a Public Health Emergency. FDIC is committed to providing all FDIC personnel with a safe and healthy work environment. When the Secretary of Health and

Human Services declares a public health emergency under Section 319 of the Public Health Act, FDIC may develop and institute additional safety measures to protect the workforce and those individuals entering FDIC facilities. These measures may include instituting activities such as requiring FDIC personnel and visitors to provide information before being allowed access to a FDIC facility, medical screening, and contact tracing. FDIC personnel may also need to provide information before being authorized to travel.FDIC will collect and maintain information in accordance with the Americans with Disabilities Act of 1990 and regulations and guidance published by the U.S. Occupational Safety and Health Administration, the U.S. Equal Employment Opportunity Commission, and the U.S. Centers for Disease Control and Prevention.

SYSTEM NAME AND NUMBER:

Ensuring Workplace Health and Safety in Response to a Public Health Emergency, FDIC–036.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained at FDIC facilities in Arlington, Virginia and regional offices. Original and duplicate systems may exist, in whole or in part, at secure sites and on secure servers maintained by third-party service providers for the FDIC.

SYSTEM MANAGER(S):

Special Advisor to FDIC's Chief Operating Officer, 3501 Fairfax Drive, Arlington, VA 22226, *healthandsafety@fdic.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 9, 11, and 12 of the Federal Deposit Insurance Act (12 U.S.C. 1819, 1821, and 1822); American with Disabilities Act, including 42 U.S.C. 12112(d)(3)(B), 29 CFR 1630.2(r), 1630.14(b), (c), (d)(4); Title VII of the Civil Rights Act, 42 U.S.C. 2000e; 29 U.S.C. 791; Workforce safety federal requirements, including the Occupational Safety and Health Act of 1970, 5 U.S.C. 7902; 29 U.S.C. Chapter 15 (*e.g.,* 29 U.S.C. 668), 29 CFR part 1904, 29 CFR 1910.1020, and 29 CFR 1960.66; Executive Order 13164; Executive Order 12196; Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees dated September 9, 2021; Executive Order 14042, Ensuring Adequate COVID Safety Protocols for Federal Contractors.

PURPOSE(S) OF THE SYSTEM:

The information in the system is collected to assist the FDIC with maintaining a safe and healthy workplace and respond to a public health emergency (as defined by the U.S. Department of Health and Human Services and declared by its Secretary), such as a pandemic or epidemic. These measures may include instituting activities such as requiring FDIC personnel to provide information before being allowed access to a FDIC facility, medical screening, contact tracing, to provide information before being authorized to travel, and to comply with applicable mandates related to a public health emergency. These measures may also include requiring visitor information to determine whether to admit an individual to an FDIC facility and to conduct contract tracing when necessary for those who have visited.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by this system include FDIC personnel (including political appointees, onboarding employees, employees, detailees, contractors, consultants, interns, and volunteers) and visitors to a FDIC facility during a public health emergency, such as a pandemic or epidemic. FDIC may also maintain information on FDIC personnel's emergency contacts.

CATEGORIES OF RECORDS IN THE SYSTEM:

FDIC personnel information may include:

- Name;
- Contact information (*e.g.,* email address, phone number);
- Recent travel history;
- Whether they provide dependent care for an individual in a high-risk category;
- Health information, including:
  - Body temperature,
  - Confirmation of pathogen or communicable disease test,
  - Test results,
  - Dates, symptoms, potential or actual exposure to a pathogen or communicable disease,
  - Immunization or vaccination information, and
  - Information to support a request for exemption from a vaccination (*e.g.,* medical diagnosis or religious beliefs);
- Contact tracing information, including:
  - Dates when they visited the FDIC facility,
  - Locations that they visited within the facility (*e.g.,* office and cubicle number),
  - Duration of time spent in the facility, and
  - Whether they may have potentially come into contact with a contagious person while visiting the facility.

Information about visitors to FDIC facilities may include:

- Name;
- Contact information;
- Recent travel history;
- Health information, including:
  - Body temperature,
  - Confirmation of pathogen or communicable disease test,
  - Test results,
  - Dates, symptoms, potential or actual exposure to a pathogen or communicable disease, and
  - Attestation of vaccine status;
- Contact tracing information, including:
  - Dates when they visited the FDIC facility,
  - Locations that they visited within the facility (*e.g.,* office and cubicle number),
  - Duration of time spent in the facility, and
  - Whether they may have potentially come into contact with a contagious person while visiting the facility.

Information about emergency contacts may include:

- Name,
- Phone number, and
- Email addresses.

RECORD SOURCE CATEGORIES:

The information in this system is collected in part directly from the individual or from the individual's emergency contact. Information is also collected from security systems monitoring access to FDIC facilities, such as video surveillance and turnstiles, human resources systems, emergency notification systems, and federal, state, and local agencies assisting with the response to a public health emergency. Information may also be collected from property management companies responsible for managing office buildings that house FDIC facilities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside the FDIC as a routine use as follows:

(1) To appropriate Federal, State, local and foreign authorities responsible for investigating or prosecuting a violation of, or for enforcing or implementing a statute, rule, regulation, or order issued, when the information indicates a

violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto;

(2) To a court, magistrate, or other administrative body in the course of presenting evidence, including disclosures to counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal proceedings, when the FDIC is a party to the proceeding or has a significant interest in the proceeding, to the extent that the information is determined to be relevant and necessary;

(3) To a congressional office in response to an inquiry made by the congressional office at the request of the individual who is the subject of the record;

(4) To appropriate agencies, entities, and persons when (a) the FDIC suspects or has confirmed that there has been a breach of the system of records; (b) the FDIC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the FDIC (including its information systems, programs, and operations), the Federal Government, or national security; the FDIC and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the FDIC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm;

(5) To another Federal agency or Federal entity, when the FDIC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) 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;

(6) To contractors, grantees, volunteers, and others performing or working on a contract, service, grant, cooperative agreement, or project for the FDIC, the Office of Inspector General for the purpose of assisting FDIC respond to a public health emergency;

(7) To a Federal, State, or local agency to the extent necessary to comply with laws governing reporting of infectious disease; and

(8) To the FDIC personnel member's emergency contact for purposes of locating a personnel member during a public health emergency or to communicate that the FDIC personnel member may have potentially been exposed to a virus as the result of a pandemic or epidemic while visiting a FDIC facility.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored in electronic media and in paper format within individual file folders.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Electronic media and paper format are indexed and retrieved by employee name, employee identification number, office location, or office/division name.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

FDIC is in the process of creating a new records schedule for declared public health emergencies. FDIC maintains emergency contact information until superseded or obsolete, or upon separation or transfer of employee.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Electronic records are password-protected and accessible only by authorized personnel. Paper records are maintained in lockable file cabinets accessible only to authorized personnel.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to records about them in this system of records must submit their request in writing to the FDIC FOIA & Privacy Act Group, 550 17th Street NW, Washington, DC 20429, or email *efoia@fdic.gov.* Requests must include full name, address, and verification of identity in accordance with FDIC regulations at 12 CFR part 310.

CONTESTING RECORD PROCEDURES:

Individuals wishing to contest or request an amendment to their records in this system of records must submit their request in writing to the FDIC FOIA & Privacy Act Group, 550 17th Street NW, Washington, DC 20429, or email *efoia@fdic.gov.* Requests must specify the information being contested, the reasons for contesting it, and the proposed amendment to such information in accordance with FDIC regulations at 12 CFR part 310.

NOTIFICATION PROCEDURES:

Individuals wishing to know whether this system contains information about them must submit their request in writing to the FDIC FOIA & Privacy Act Group, 550 17th Street NW, Washington, DC 20429, or email *efoia@fdic.gov.* Requests must include full name, address, and verification of identity in accordance with FDIC regulations at 12 CFR part 310.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on November 9, 2021.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2021–24894 Filed 11–15–21; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than December 16, 2021.

A. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent

electronically to *Comments.applications@phil.frb.org:*

1. *Riverbank Financial, MHC, Carthage, New York;* to become a Delaware-chartered mutual bank holding company, and its mid-tier holding company, Riverbank Financial Corporation, to become a Maryland-chartered stock bank holding company, upon the conversion of Carthage Federal Savings & Loan Association, both of Carthage, New York, from a federal stock savings and loan association to a national bank.

Board of Governors of the Federal Reserve System, November 10, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–24977 Filed 11–15–21; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Trade Commission (FTC or Commission).

ACTION: Notice.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act (PRA). The FTC seeks public comments on the agency's shared enforcement with the Consumer Financial Protection Bureau (CFPB) of the information collection requirements in subpart N of the CFPB's Regulation V (Rule). That clearance expires on February 28, 2022.

DATES: Comments must be received on or before January 18, 2022.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comments part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Regulation V, subpart N; PRA Comment: FTC File No. P072108'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the collection of information and supporting documentation should be addressed to Ryan Mehm, Attorney, Bureau of Consumer Protection, (202) 326–2918, Federal Trade Commission, 600 Pennsylvania Ave. NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: *Title:* Regulation V, Subpart N (12 CFR 1022.130–1022.138).

OMB Control Number: 3084–0128.

Type of Review: Extension of a currently approved collection.

Abstract: The FTC shares enforcement authority with the CFPB for subpart N of Regulation V. Subpart N requires nationwide consumer reporting agencies and nationwide consumer specialty reporting agencies to provide to consumers, upon request, one free file disclosure within any 12-month period. Generally, it requires the nationwide consumer reporting agencies, as defined in Section 603(p) of the Fair Credit Reporting Act (FCRA), 15 U.S.C. 1681a(p), to create and operate a centralized source that provides consumers with the ability to request their free annual file disclosures from each of the nationwide consumer reporting agencies through a centralized internet website, toll-free telephone number, and postal address. Subpart N also requires the nationwide consumer reporting agencies to establish a standardized form for internet and mail requests for annual file disclosures and provides a model standardized form that may be used to comply with that requirement. It additionally requires nationwide specialty consumer reporting agencies, as defined in Section 603(w) of the FCRA, 15 U.S.C. 1681a(w), to establish a streamlined process for consumers to request annual file disclosures. This streamlined process must include a toll-free telephone number for consumers to make such requests.

As required by section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), the FTC is providing this opportunity for public comment before requesting that OMB extend the existing clearance for the information collection requirements contained in the Rule.

Burden Statement

Because the FTC shares enforcement authority with the CFPB for subpart N, the two agencies split between them the related estimate of PRA burden for firms under their co-enforcement jurisdiction. Estimated PRA burden, excluding the halving (to be shown at the conclusion of this analysis), are as follows:

A. Requests per Year From Consumers for Free Annual File Disclosures

When the FTC last sought clearance renewal for the Rule, the Consumer Data Industry Association (''CDIA'') estimated that in 2016 and 2017, the nationwide consumer reporting agencies provided on average approximately 25 million free annual file disclosures through the centralized internet website required to be established by the FACT Act and subpart N. Based on its knowledge of the industry, FTC staff projected that the consumer reporting agencies provided no more than 6 million free annual file disclosures through the centralized toll-free telephone number and postal address required to be established by the FACT Act and subpart N. Accordingly, we estimated 31 million requests per year as a representative average to calculate PRA burden. We expect that the number of requests for free annual credit reports will rise over the next three years because of increases in the population and consumer awareness that they are entitled to a free annual report. As a proxy, we are now estimating 34 million requests per year as a representative average year to estimate PRA burden for purposes of the instant analysis.

The Commission, however, seeks more recent estimates of the number of requests consumers are making for free annual credit reports. In addition to data on the number of requests, data on how the number of requests has changed over time, and how these requests are being received—by internet, phone, or by mail—would be most helpful.

B. Annual File Disclosures Provided Through the Internet

Both nationwide and nationwide specialty consumer reporting agencies will likely handle the overwhelming majority of consumer requests through internet websites. The annual file disclosure requests processed through the internet will impose a *de minimis* hourly burden in personnel costs per request on the nationwide and nationwide specialty consumer reporting agencies, except for those requests that are redirected to the mail process.[1] However, consumer reporting agencies periodically will be required to adjust the internet capacity needed to handle the changing request volume. Consumer reporting agencies likely will make such adjustments by negotiating or renegotiating outsourcing service contracts annually or as conditions

[1] *See infra* note 5.

change. Trained personnel will need to spend time negotiating and renegotiating such contracts. Commission staff estimates that negotiating such contracts will require a cumulative total of 8,320 hours and $646,963 in labor costs.[2] Such activity is treated as an annual burden of maintaining and adjusting the changing internet capacity requirements.

C. Annual File Disclosures Requested Over the Telephone

Most of the telephone requests for annual file disclosures will also be handled in an automated fashion, with *de minimis* personnel costs needed to process the requests except for those requests that are redirected to the mail process.[3] As with the internet, consumer reporting agencies will require additional time and investment to increase and administer the automated telephone capacity for the expected increase in request volume. The nationwide and nationwide specialty consumer reporting agencies will likely make such adjustments by negotiating or renegotiating outsourcing service contracts annually or as conditions change. Staff estimates that this will require a total of 6,240 hours at a cost of $485,222 in labor costs.[4] This activity also is treated as an annual recurring burden necessary to obtain, maintain, and adjust automated call center capacity.

D. Annual File Disclosures Requiring Processing by Mail

Based on their knowledge of the industry, staff believes that no more than 1% of consumers (1% × 34 million, or 340,000) will request an annual file disclosure through U.S. postal service mail. Staff estimates that clerical personnel will require 10 minutes per request to handle these requests, thereby totaling 56,667 hours of time. [(340,000 × 10 minutes)/60 minutes per hour = 56,667 hours]

In addition, whenever the requesting consumer cannot be identified using an automated method (a website or automated telephone service), it will be necessary to redirect that consumer to send identifying material along with the request by mail. Staff estimates that this will occur in about 5% of the new requests (or 1,683,000)[5] that were originally placed over the internet or telephone. Staff estimates that clerical personnel will require approximately 10 minutes per request to input and process those redirected requests for a cumulative total of 280,500 clerical hours. [(1,683,000 × 10 minutes)/60 minutes per hour = 280,500 hours]

E. Instructions to Consumers

The Rule also requires that certain instructions be provided to consumers. *See* Rule sections 1022.136(b)(2)(iv)(A–B), 1022.137(a)(2)(iii)(A–B). Minimal associated time or cost is involved, however. Internet instructions to consumers are embedded in the centralized source website and do not require additional time or cost for the nationwide consumer reporting agencies. Similarly, for telephone requests, the automated phone systems provide the requisite instructions when consumers select certain options. Some consumers who request their credit reports by mail might additionally request printed instructions from the nationwide and nationwide specialty consumer reporting agencies. Staff estimates that there will be a total of 2,023,000 requests each year for free annual file disclosures by mail.[6] Based on their knowledge of the industry, staff estimates that, of the predicted 2,023,000 mail requests, 10% (or 202,300) will request instructions by mail. If printed instructions are sent to each of these consumers by mail, requiring 10 minutes of clerical time per consumer, this will total 33,717 hours. [(202,300 instructions × 10 minutes)/60 minutes per hour].

F. Labor Costs

Labor costs are derived by applying hourly cost figures to the burden hours described above. Staff anticipates that processing of requests for annual file disclosures and instructions will be performed by clerical personnel and estimates that the processing will require 370,884 hours at a cost of $7,013,416. [(56,667 hours for handling initial mail requests + 280,500 hours for handling requests redirected to mail + 33,717 hours for handling instructions mailed to consumers) × $18.91 per hour.[7]]

As elaborated on above, staff estimates that a total of 14,560 labor hours will be needed to negotiate or renegotiate outsourced service contracts annually (or as conditions otherwise change) to increase internet (8,320 hours) and telephone (6,240 hours) capacity requirements for internet web services and the automated telephone call center. This will result in approximately $1,132,186 per year in labor costs. [14,560 hours × $77.76 per hour[8]]

Thus, estimated cumulative labor costs are $8,145,602.

G. Capital/Non-Labor Costs

As in the previous PRA clearance analysis, FTC staff believes it is likely that consumer reporting agencies will use third-party contractors (instead of their own employees) to increase the capacity of their systems. Because of the way these contracts are typically established, these costs will likely be incurred on a continuing basis and will be calculated based on the number of requests handled by the systems. Staff estimates that the total annual amount to be paid for services delivered under these contracts is $12,454,200.[9]

H. Net Burden for FTC, After 50:50 Split

After halving the updated estimates to split the PRA burden with the CFPB regarding the Rule, the FTC's burden totals are 192,722 hours, $4,072,801 in associated labor costs, and $6,227,100 in non-labor/capital costs.

Request for Comments

Pursuant to Section 3506(c)(2)(A) of the PRA, the FTC invites comments on: (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

[2] Based on the time necessary for similar activity in the federal government (including at the FTC), staff estimates that such contracting and administration will require approximately 4 full-time equivalent employees (FTE) for the web service contracts. Thus, staff estimates that administering the contract will require four FTE, which is 8,320 hours per year (four FTE × 2,080 hours/year). The cost is based on the reported May 2020 Bureau of Labor Statistics (BLS) rate ($77.76) for computer and information systems managers. *See Occupational Employment and Wages—May 2020,* Table 1, *available at https://www.bls.gov/news.release/pdf/ocwage.pdf.* Thus, the estimated setup and maintenance cost for an internet system is $646,963 per year (8,320 hours × $77.76/hour).

[3] *See infra* note 5.

[4] Staff estimates that recurring contracting for automated telephone capacity will require approximately 3 FTE, a total of 6,240 hours (3 × 2,080 hours). Applying an hourly wage rate of $77.76 (*see supra* note 2), estimated setup and maintenance cost is $485,222 (6,240 × $77.76) per year.

[5] This figure reflects five percent of all requests, net of the estimated one percent of all requests that might initially be made by mail. That is, 0.05 × (34,000,000 − 340,000) = 1,683,000.

[6] This figure includes both the estimated 1% of 34 million requests that will be made by mail each year (340,000), and the estimated 1,683,000 requests initially made over the internet or telephone that will be redirected to the mail process (*see supra* note 5).

[7] *See Occupational Employment and Wages—May 2020,* Table 1, *available at https://www.bls.gov/news.release/pdf/ocwage.pdf* (Office and administrative support workers, all others).

[8] *See supra* notes 2 and 4.

[9] This consists of an estimated $8,323,200 for automated telephone cost ($1.36 per request × 6.12 million requests) and an estimated $4,131,000 ($0.15 per request × 27.54 million requests) for internet web service cost. Per unit cost estimates are based on staff's knowledge of the industry.

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 maintaining records and providing disclosures to consumers. All comments must be received on or before January 18, 2022.

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before January 18, 2022. Write ''Regulation V, subpart N; PRA Comment: FTC File No. P072108'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including the *https://www.regulations.gov* website.

Due to the public health emergency in response to the COVID–19 outbreak and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''Regulation V, subpart N; PRA Comment: FTC File No. P072108'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex J), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will become publicly available at *https://www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . . is privileged or confidential'' —as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2) —including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *www.regulations.gov,* we cannot redact or remove your comment unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before January 18, 2022. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2021–25012 Filed 11–15–21; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting for Software Developers on the Common Formats for Patient Safety Data Collection

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of public meeting.

SUMMARY: AHRQ coordinates the development of sets of standardized definitions and formats (Common Formats) that make it possible to collect, aggregate, and analyze uniformly structured information about health care quality and patient safety for local, regional, and national learning. The Common Formats include technical specifications to facilitate the collection of electronically comparable data by Patient Safety Organizations (PSOs) and other entities. Additional information about the Common Formats can be obtained through AHRQ's PSO website at *https://pso.ahrq.gov/common-formats* and the PSO Privacy Protection Center's website at *https://www.psoppc.org/psoppc_web/publicpages/commonFormatsOverview.*

The purpose of this notice is to announce a meeting to discuss implementation of the Common Formats with software developers and other interested parties. This meeting is designed as an interactive forum where software developers can provide input on use of the formats. AHRQ especially requests participation by and input from those entities which have used AHRQ's technical specifications and implemented, or plan to implement, the Common Formats electronically.

DATES: The meeting will be held from 1:00 to 3:30PM Eastern on Thursday, December 16th, 2021.

ADDRESSES: The meeting will be held virtually.

FOR FURTHER INFORMATION CONTACT: Dr. Hamid Jalal, Medical Officer, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Rockville, MD 20857; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *pso@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to 299b–26 (Patient Safety Act), and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70731–70814, provide for the Federal listing of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information (patient safety work product) regarding the quality and safety of health care delivery.

The Patient Safety Act requires PSOs, to the extent practical and appropriate, to collect patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers. (42 U.S.C. 299b–24(b)(1)(F)).

The Patient Safety Act also authorizes the development of data standards, known as the Common Formats, to facilitate the aggregation and analysis of non-identifiable patient safety data collected by PSOs and reported to the network of patient safety databases (NPSD). (42 U.S.C. 299b–23(b)). The Patient Safety Act and Patient Safety Rule can be accessed at: *http://www.pso.ahrq.gov/legislation/.*

AHRQ has issued Common Formats for Event Reporting for three settings of care—hospitals, nursing homes, and community pharmacies. As part of the agency's efforts to improve diagnostic safety and quality in healthcare, AHRQ is in the process of developing Common Formats for Event Reporting—Diagnostic Safety (CFER–DS). The CFER–DS is intended to help healthcare providers identify and report missed opportunities in the diagnostic process in a standardized manner across healthcare settings and specialties. Widespread use of the CFER–DS will make it possible to collect, aggregate, and analyze diagnostic safety-related information from healthcare providers across the country, which in turn can accelerate learning in this vital area of patient safety. Public comment has been received on a version 0.1 of the CFER–DS, and an Expert Panel convened by the National Quality Forum (NQF) is currently in the process of reviewing the public comments and providing feedback to AHRQ.

Federally listed PSOs can meet the requirement to collect patient safety work product in a standardized manner to the extent practical and appropriate by using AHRQ's Common Formats. The Common Formats are also available in the public domain to encourage their widespread adoption. An entity does not need to be listed as a PSO or working with one to use the Common Formats. However, the Federal privilege and confidentiality protections only apply to information developed as patient safety work product by providers and PSOs working under the Patient Safety Act.

Each version of the Common Formats is released with accompanying technical specifications, intended to provide direction to software developers and to PSOs that plan to submit data to the Patient Safety Organization Privacy Protection Center (PSOPPC) to ensure non-identification for transmission to the NPSD. For existing Common Formats for Event Reporting, technical specifications include the following:

- Data dictionary—defines data elements and their attributes (data element name, answer values, field length, guide for use, etc.) included in Common Formats;
- Clinical document architecture (CDA) implementation guide—provides instructions for developing a file to transmit the data from the PSO to the PSOPPC using the Common Formats;
- Validation rules and errors document—specifies and defines the validation rules that will be applied to the Common Formats data elements submitted to the PSOPPC;
- Common Formats flow charts—diagrams the valid paths to complete the formats (a complete event report);
- Local specifications—provides specifications for processing, linking, and reporting on events and details specifications for reports; and
- Metadata registry—includes descriptive facts about information contained in the data dictionary to illustrate how such data corresponds with similar data elements used by other Federal agencies and standards development organizations (*e.g.,* HL—7, International Standards Organization (ISO)).

Agenda, Registration, and Other Information About the Meeting

The December 16, 2021 meeting will be an interactive forum designed to allow meeting participants not only to provide input but also to respond to the input provided by others. The meeting agenda will include: An update of Federal efforts related to the PSO Program and Common Formats; discussion of the CFER–DS, including requesting feedback on planned technical support materials and general integration/implementation; and, planning for future meetings, including discussing potential topics of interest for regular future meetings with software developers. AHRQ requests that interested persons send an email to *SDMeetings@infinityconferences.com* for registration information. Before the meeting, an agenda and logistical information will be provided to registrants. Prior to the meeting, AHRQ invites review of the CFER–DS which can be accessed through NQF's website at *https://www.qualityforum.org/Common_Formats_for_Patient_Safety_Data.aspx.*

Dated: November 9, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–24888 Filed 11–15–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60 Day–2–0059; Docket No. ATSDR–2021–0008]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Per-or-Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs). This Revision information collection request (ICR) will allow ATSDR/NCEH to continue to conduct additional Exposure Assessments (EAs) that may be requested at military or non-military installations.

DATES: ATSDR must receive written comments on or before January 18, 2022.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR–2021–0008 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. ATSDR will post, without change, all relevant comments to *Regulations.gov*.

Please note: *Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office,

Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; phone: 404–639–7118; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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 estimate 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;
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 submissions of responses; and
5. Assess information collection costs.

Proposed Project

Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs) (OMB Control No. 0923–0059, Exp. 06/30/2022)—Revision—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

Per-or-polyfluoroalkyl substances (PFAS) are contaminants that have gained national prominence over the last decade. PFAS are a large group of man-made chemicals that have been used in industry and consumer products worldwide since the 1950s. Although some PFAS are no longer produced in the United States, many remain in the environment and may impact people's health.

The Agency for Toxic Substances and Disease Registry (ATSDR) and the National Center for Environmental Health (NCEH) are requesting a three-year revision information collection request (ICR) to continue to conduct PFAS exposure assessments (EAs) at both military or non-military locations known to have PFAS in drinking water, groundwater, or any other sources of water. Previously, ATSDR was approved to conduct up to five EAs per year, for which the agency completed a total of eight. Currently, ATSDR is seeking approval to conduct up to three EAs per year for a maximum of seven additional locations.

Originally authorized under the National Defense Authorization Act (NDAA) of 2018, ATSDR is also mandated under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), commonly known as the ''Superfund'' Act, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986, to prevent or mitigate adverse human health effects and diminished quality of life resulting from the exposure to hazardous substances in the environment. NCEH can conduct EAs under the authority of Section 301 of the Public Health Service Act (42 U.S.C. 241).

The PFAS EAs are conducted using statistical sampling to produce unbiased estimates of exposure to PFAS in communities living on or near the chosen current or former military installations. The number of respondents per EA will vary, but we expect the number to be approximately 395, and to be determined by specific statistical methods.

The time burden associated with the EAs include the following collections:

- *Community Event Evaluation Survey:* ATSDR/NCEH will hold a public meeting prior to the start of the EA and attendees will be asked to complete a five minute Community Event Evaluation Survey. It is assumed that 163 of the 250 attendees will complete the survey at each EA site, resulting in a burden of 41 hours for three EAs.
- *Household Eligibility Screener:* ATSDR/NCEH anticipates asking approximately 269 adults in each household at each EA site to complete a five minute telephone script, resulting in a burden of 66 hours for three EAs.
- *Estimation of Number of EA Respondents by Age Group:* Based on the criteria in the Household Recruitment Phone Script, 149 households are assumed to provide the target sample size of 395 respondents at each EA site, with a total of 1,185 respondents for three EAs. Based on 2017 Census estimates of average household size (2.5), and number of adults (1.9), and children under 18 years of age (0.6) in the household, we are able to estimate the annual number of respondents by age group as the following for three EAs: 900 adults ≥18 years and 284 children (165 aged 3–11 years and 119 aged 12–17 years).
- *Biological Testing Tracking:* All of the EAs use biological sampling for PFAS (blood and urine). A biological testing tracking form for the testing event will be provided to ensure that all appropriate forms are completed and all biological samples are collected. The testing will take 20 minutes, resulting in a burden of 395 hours annually for three EAs.
- *Adult Consent for Biological Testing:* 300 adults at each EA site will be administered a 10-minute consent form for testing of blood and urine for PFAS, resulting in a burden of 150 hours annually for three EAs.
- *Parental Permission Form for Biological Testing:* A parental permission form will be administered to the parents of 284 children aged 3–17 years for testing of blood and urine. The parental permission form will take 10 minutes resulting in a burden of 47 hours annually for three EAs.
- *Child Assent Form for Biological Testing:* Children aged 12–17 years (119) will assent to the testing of blood and urine for PFAS. The child assent form will take approximately 10 minutes, resulting in a burden of 20 hours annually for three EAs.
- *Adult Exposure Questionnaire for Biological and Environmental Testing:* 300 adults at each EA site will be administered an exposure questionnaire. The time associated with administering the questionnaire and completing the biological sampling is approximately 30 minutes, resulting in a burden of 450 hours annually for three EAs.
- *Parent Proxy for Child Exposure Questionnaire for Biological Testing:* 165 parents will respond to the 15-minute questionnaire for their children, 3–11 years, resulting in a burden of 41 hours annually for three EAs.
- *Child Exposure Questionnaire for Biological Testing:* Annually, 119 children will respond to the 15-minute child questionnaire for themselves (age 12–17 years), resulting in a burden of 30 hours annually for three EAs.
- *Household Recruitment Script for Environmental Testing:* ATSDR/NCEH will administer a five minute environmental recruitment script to 69 heads of households, resulting in a burden of six hours annually for three EAs.

• *Consent for Environmental Testing:* ATSDR/NCEH will obtain consent to test 10% of EA households for tap water and indoor dust samples using a 10-minute consent form for an annual total of 45 households, resulting in burden of eight hours annually for three EAs.

Environmental Sample Collection: ATSDR/NCEH will complete sampling at 45 households for three EAs deemed eligible for the EA for testing of tap water and indoor dust samples. The sampling will take 30 minutes, for an estimated burden of 23 hours annually for three EAs.

ATSDR estimates the annualized time burden is 1,277 hours. Participation is voluntary, and there are no costs to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
EA Community Members	Community Event Evaluation Survey	489	1	5/60	41
EA Participants (all ages)	Biological Testing Tracking	1,185	1	20/60	395
EA Adults	Household Eligibility Screener	807	1	5/60	66
	Consent	900	1	10/60	150
	Exposure Questionnaire (Adult) for Biological and Environmental Testing.	900	1	30/60	450
EA Parents	Parental Permission	284	1	10/60	47
	Exposure Questionnaire (Child) for Biological Testing (Parent Proxy).	165	1	15/60	41
EA Children	Assent	119	1	10/60	20
	Exposure Questionnaire (Child) for Biological Testing (Child completed).	119	1	15/60	30
EA Heads-of-Households	Household Recruitment Script for Environmental Sampling.	69	1	5/60	6
	Environmental Sampling Consent Form	45	1	10/60	8
	Environmental Sample Collection Form	45	1	30/60	23
Total					1,277

Jeffrey M. Zirger,

Lead,Information Collection Review Office,Office of Scientific Integrity,Office of Science,Centers for Disease Control and Prevention.

[FR Doc. 2021–24992 Filed 11–15–21; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day–22–0047]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on March 26, 2021, to obtain comments from the public and affected agencies. ATSDR did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies 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;

(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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (OMB Control No. 0923–0047, Exp. 01/31/2022)—Extension—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Federal government's commitment to improving service delivery. By qualitative feedback we mean information that provides

useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study.

This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

ATSDR will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are noncontroversial and do not raise issues of concern to other Federal agencies;
- Any collection is 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;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered is intended to be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency (if released, the agency must indicate the qualitative nature of the information);
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential nonresponse bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

This is an extension of the previously approved collection. There is no cost to respondents other than their time. The total estimated annualized burden is 7,075 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Type of collection	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Individuals and Households; Businesses and Organizations; State, Local, or Tribal Government.	Small discussion groups	300	1	90/60
	Request for customer comment cards/complaint forms/post-conference or training surveys.	1,500	1	15/60
	Focus groups of customers, potential customers, delivery partners, or other stakeholders.	2,000	1	2
	Qualitative customer satisfaction surveys or interviews.	3,000	1	30/60
	Usability testing/in-person observation testing	1,500	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–24990 Filed 11–15–21; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–1046]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Monitoring Activities to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on July 26, 2021 to obtain comments from the public and affected agencies. CDC received one non-substantive comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies 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;

(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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Monitoring Activities—(OMB Control No. 0920–1046, Exp. 11/30/2021)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting a Revision of the Information Collection Request (ICR) titled National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Monitoring Activities (OMB Control No. 0920–1046). In the previous OMB approval period, information collection consisted of an annual NBCCEDP survey and clinic-level data collection. In the next OMB approval period, information collection will consist of a revised NBCCEDP survey, revised clinic-level data collection, new quarterly program update, new service delivery projection worksheet, and the addition of previously approved minimum data elements (MDEs; OMB Control No. 0920–0571, Exp. 03/31/2022) to increase efficiency. The number of respondents will remain the same and the total estimated annualized burden will increase from 683 to 1,228.

Breast and cervical cancers are prevalent among U.S. women. Evidence shows that deaths from both breast and cervical cancers can be avoided by increasing screening services—mammography and pap tests—among women. However, screening is typically underutilized among women who are under- or uninsured, have no regular source of healthcare, or who recently immigrated to the U.S. To improve access to cancer screening, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Pub. L. 106–354) which directed CDC to create the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The NBCCEDP currently provides funding to 70 awardees under ''Cancer Prevention and Control Programs for State, Territorial, and Tribal Organizations (DP17–1701).'' The purpose of NBCCEDP is to increase breast and cervical cancer screening rates among women residing within defined geographical locations (as determined by the funded program) who are at or below 250% of the federal poverty level; aged 40–64 years for breast cancer services, and aged 21–64 years for cervical cancer services; and under- or uninsured.

In 2022, CDC will issue a new Notice of Funding Opportunity (DP22–2202) to continue this mission. Consistent with programmatic changes, the information collection plan has also been redesigned to update existing and add new data collection instruments and integrate the previously approved MDEs into this single approval package to increase efficiency of information collection for the NBCCEDP.

CDC proposes five forms of information collection. First, the NBCCEDP Survey will be submitted to CDC annually and collects information to monitor awardees' TA needs, partnerships, screening delivery, EBI implementation, and COVID–19 impact. Minor revisions to survey questions, response options, and formatting will be included under DP22–2202. Second, clinic-level data will be submitted to CDC at baseline and annually for all partnering health system clinic sites—an estimated six clinics per awardee for breast cancer data and six clinics per awardee for cervical cancer data. Clinic-level data includes health system, clinic, and patient population characteristics; monitoring and quality improvement activities; EBI implementation; COVID–19 impact, and baseline or annual screening rates. Minor revisions were made to variable wording, formatting (*e.g.,* split or combined variables), and response options to improve data quality. Third, the Quarterly Program Update (QPU) will be submitted to CDC four times per year to monitor award spending, service delivery, staff vacancies, and program accomplishments and challenges. This is a new information collection. Fourth, the Service Delivery Projection Worksheet will be submitted to CDC annually to report the estimated number of women to be served for breast and cervical cancer. Finally, the Minimum Data Elements (MDEs) will be submitted to CDC twice per year to monitor patient demographics; breast and cervical cancer screening, diagnosis, and treatment; timeliness of services; and patient navigation. This information collection was previously approved (OMB Control No. 0920–0571, Exp. 03/30/2022) and will now be incorporated into this OMB approved package for increased efficiency for NBCCEDP information collection efforts.

This revised information collection will allow CDC to provide routine monitoring feedback to awardees based on their data submissions, tailor technical assistance (TA) as needed, support program planning, and assess program outcomes. OMB approval is requested for three years. Participation is required for NBCCEDP awardees. There are no costs to respondents other than their time. The total estimated annual burden is 1,228 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)
NBCCEDP Awardees	Annual NBCCEDP Survey	70	1	56/60
	NBCCEDP Clinic-level Information Collection Instrument—Breast.	70	6	45/60
	NBCCEDP Clinic-level Information Collection Instrument—Cervical.	70	6	45/60
	Quarterly Program Update	70	4	32/60
	Service Delivery Projection Worksheet	70	1	29/60
	MDEs	70	2	150/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–24989 Filed 11–15–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–1105; Docket No. CDC–2021–0117]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled the One Health Harmful Algal Bloom System (OHHABS). OHHABS is a surveillance platform which captures data on harmful algal bloom (HAB) events and HAB-associated illnesses.

DATES: CDC must receive written comments on or before January 18, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0117 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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 estimate 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;
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 submissions of responses; and
5. Assess information collection costs.

Proposed Project

One Health Harmful Algal Bloom System (OHHABS) (OMB Control No. 0920–1105, Exp. 3/31/2022)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Algal toxins from harmful algal blooms (HABs) include some of the most potent natural chemicals. These toxins can contaminate surface water used for recreation and drinking, as well as food sources, and HABs pose a threat to both humans and animals. Because animal illness may be an indicator of bloom toxicity, it is necessary to provide a One Health approach for reporting HAB-associated illnesses and events.

The One Health Harmful Algal Bloom System (OHHABS) was approved for data collection in 2016 and collects data on harmful algal blooms (HABs) and human and animal illnesses related to HAB exposures to support the understanding of HABs and the prevention of HAB-associated illnesses. As such, OHHABS is a centralized data source for voluntary public health surveillance of HAB events and HAB-associated illnesses using a One Health approach that takes into consideration information from the environment, animal cases, and human cases.

CDC requests OMB approval for an estimated 76 annual burden hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
OHHABS State Reporting Sites.	One Health Harmful Algal Bloom System (OHHABS) (electronic, year-round).	57	4	20/60	80/60
Total	.....	.....	.....	.....	76

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–24993 Filed 11–15–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–0920]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''*Data Collection Through Web Based Surveys for Evaluating Act Against AIDS Social Marketing Campaign Phases Targeting Consumers,*'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on September 7, 2021 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies 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;

(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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Data Collection Through Web Based Surveys for Evaluating Act Against AIDS Social Marketing Campaign Phases Targeting Consumers (OMB Control No. 0920–0920, Exp. 11/30/2021)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In response to the continued HIV epidemic in our country, CDC launched the Let's Stop HIV Together campaign (formerly known as Act Against AIDS), a multifaceted communication campaign to reduce HIV incidence in the United States in 2009. CDC has released the campaign in phases, with some of the phases running concurrently. Each phase of the campaign uses mass media and direct-to-consumer channels to deliver messages. Some campaigns provide basic education and increase awareness of HIV/AIDS among the general public, whereas others emphasize HIV prevention and testing among specific subgroups or communities at greatest risk of infection. CDC will also develop new messages to address changes in prevention science and subpopulations affected by HIV. The proposed study will assess the effectiveness of these social marketing messages aimed at increasing HIV/AIDS awareness, increasing prevention behaviors, and improving HIV testing rates among consumers.

This Extension of an ongoing study will allow for continued evaluation of the effectiveness of Let's Stop HIV Together social marketing campaign through surveys with consumers. A total of 6,445 respondents were approved for the previously renewed Generic ICR (0920–0920) in 2018, and since the approval date, 1,000 respondents were surveyed under the GenIC, ''Development of Messages for the Let's Stop HIV Together National Campaign''. The information collected from this survey was used to evaluate the acceptability and potential effectiveness of proposed concepts, messages, and taglines for a component of the Let's

Stop HIV Together campaign focused on HIV prevention that promotes proven, effective prevention strategies, such as pre-exposure prophylaxis (PrEP) and treatment as prevention (TasP). We are requesting a one-year extension to continue surveying target audiences.

Through this extension, we plan to reach the remaining approved 5,445 respondents. To obtain the remaining respondents, we anticipate screening approximately 30,880 individuals. Depending on the target audience for the campaign phase, the study screener will vary. The study screener may address one or more of the following items: Race/ethnicity, sexual behavior, sexual orientation, gender identity, HIV testing history, HIV status, and injection drug use. Each survey will have a core set of items asked in all rounds, as well as a module of questions relating to specific Let's Stop HIV Together phases and activities.

Respondents will be recruited through national opt-in email lists, the internet, and external partnerships with community-based and membership organizations that work with or represent individuals from targeted populations (*e.g.,* National Urban League, the National Medical Association). Respondents will self-administer the survey at home on personal computers. The annual response burden is estimated at 3,751 hours. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)
Individuals (male and female) aged 18 years and older	Study Screener	30,880	1	2/60
	Survey Module	5,445	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–24991 Filed 11–15–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–1318; Docket No. CDC–2021–0124]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Requirement for Negative Pre-Departure COVID–19 Test Result or Documentation of Recovery from COVID–19 For All Airline or Other Aircraft Passengers Arriving into the United States from any Foreign Country and Requirement for Proof of COVID–19 Vaccination for Noncitizen, Nonimmigrant Air Passengers Arriving Into The United States From A Foreign Country. This proposed information collection is designed to ensure that CDC complies with Orders published October 25 and October 30, 2021, and to confirm that passengers who are coming into the United States via air travel have tested negative for or recently recovered from COVID–19, and that noncitizen, nonimmigrant passengers are fully vaccinated against COVID–19.

DATES: CDC must receive written comments on or before January 18, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0124 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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 estimate 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;

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 submissions of responses; and

5. Assess information collection costs.

Proposed Project

Requirement for Negative Pre-Departure COVID–19 Test Result or Documentation of Recovery from COVID–19 For All Airline or Other Aircraft Passengers Arriving into the United States from any Foreign Country and Requirement for Proof of COVID–19 Vaccination for Noncitizen, Nonimmigrant AirPassengers Arriving Into The United States From A Foreign Country (OMB Control No. 0920–1318, Exp. 5/31/2022)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Since January 2020, the respiratory disease known as ''COVID–19,'' caused by a novel coronavirus (SARS–CoV–2), has spread globally, including cases reported in all 50 states within the United States, plus the District of Columbia and all U.S. territories. As of October 22,2021, there have been over 242,000,000 million cases of COVID–19 globally, resulting in over 4,900,000 deaths. More than 45,000,000 cases have been identified in the United States, with new cases reported daily, and over 733,000 deaths have been attributed to the disease. Many countries have begun widespread vaccine administration; however, 98 countries continue to experience high or substantial incidence rates (>50 cases per 100,000 people in the last seven days) and 65 countries, including the United States, are experiencing a high incidence of reported new cases at this time.[19]

SARS–CoV–2 spreads mainly from person-to-person through respiratory fluids released during exhalation, such as when an infected person coughs, sneezes, or talks. Exposure to these respiratory fluids occurs in three principal ways: (1) Inhalation of very fine respiratory droplets and aerosol particles, (2) deposition of respiratory droplets and particles on exposed mucous membranes in the mouth, nose, or eye by direct splashes and sprays, and (3) touching mucous membranes with hands that have been soiled either directly by virus-containing respiratory fluids or indirectly by touching surfaces with virus on them. Spread is more likely when people are in close contact with one another (within about 6 feet), especially in crowded or poorly ventilated indoor settings. Persons who are not fully vaccinated, including those with asymptomatic or pre-symptomatic infections, are significant contributors to community SARS–CoV–2 transmission and occurrence of COVID–19. New variants of SARS-CoV–2 have emerged globally, several of which have been identified as variants of concern, including the Delta variant. Some variants are more transmissible and some may cause more severe disease, which can lead to more hospitalizations, and deaths among infected individuals.

On October 25, 2021 CDC amended its January 25, 2021 Order, titled, ''*Requirement for Proof of Negative COVID–19 Test or Recovery from COVID–19 for All Air Passengers Arriving in the United States.*'' This amendment updates COVID–19 testing requirements for air passengers two years or older boarding a flight to the United States, depending on COVID–19 vaccination status. Those who are fully vaccinated will need to provide a negative pre-departure COVID–19 test conducted with a specimen no more than 3 days before travel to the US, as well as proof of being fully vaccinated. While those who are not fully vaccinated will need to provide a negative pre-departure COVID–19 test conducted with a specimen no more than one day of before travel to the U.S.

The Order requiring a negative COVID–19 test or documentation of recovery has a list of categorical exemptions that would not be subject to this information collection. These include, crew members of airlines or other aircraft operators who follow industry standard protocols for the prevention of COVID–19; airlines or other aircraft operators transporting passengers with COVID–19 pursuant to CDC authorization and in accordance with CDC guidance; U.S. federal law enforcement personnel on official orders; U.S. military personnel, including civilian employees, dependents, contractors, and other U.S. government employees when traveling on U.S. military assets; and any person who may apply and receive a time limited exemption for urgent humanitarian reasons.

Also on October 25, 2021, President Biden issued a Proclamation ''*Advancing Safe Resumption of Global Travel During the COVID–19 Pandemic*''. This Proclamation allowed CDC to issue an *Order Implementing Proclamation on Advancing Safe Resumption of Global Travel During the COVID–19 Pandemic* on October 25, 2021, followed by an amendment on October 30, 2021 which provided minimal updates and superseded the October 25, 2021 Order.

This Proclamation and Order will only apply to noncitizen, nonimmigrants. It will not apply to any person who is a U.S. citizen, U.S. national, lawful permanent resident, or immigrant. The Proclamation also does not apply to crew members of airlines or other aircraft operators if they follow industry standard protocols for the prevention of COVID–19. Some noncitizen, nonimmigrants who are not fully vaccinated, as defined by the Order, may fall into a category that allows them to be excepted to the requirement if they can present to an airline or aircraft operator that they meet the criteria for that category, such as letters confirming registration in a vaccine clinical trial, or U.S. military identification.

For information collection activities associated with these Orders, CDC requests OMB approval for an estimated 352,538,030 annual burden hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Air Passenger	Section 1 of Combined Passenger Disclosure and Attestation to the United States of America.	123,000,000	1	2	246,000,000
Noncitizen Nonimmigrant Air Passenger.	Section 2 of Combined Passenger Disclosure and Attestation to the United States of America.	90,000,000	1	1	90,000,000

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Airline Desk Agent	Combined Passenger Disclosure and Attestation to the United States of America.	123,000,000	1	8/60	16,400,000
Air Passenger	Request Humanitarian Exemption to COVID–19 Test or Documentation of Recovery.	600	1	2	1,000
Noncitizen Nonimmigrant Air Passenger.	Request Humanitarian or Emergency Exception to Proof of Vaccination Requirement.	600	1	2	1,000
Air Passenger *(undergoing compliance check).*	Questions Asked to Air Passengers Going Through Compliance Checks.	1,230,000	1	5/60	102,500
Air Passenger *(undergoing compliance check with non-compliant documentation).*	Air Travel Illness or Death Investigation or Traveler Follow-up Form.	7,380	1	10/60	1,230
Noncitizen Nonimmigrant Air Passenger *(undergoing compliance check and using humanitarian or emergency exception).*	Air Travel Illness or Death Investigation or Traveler Follow-up Form.	190,000	1	10/60	31,667
Air Traveler *(for illness or death investigation).*	Air Travel Illness or Death Investigation or Traveler Follow-up Form.	1,700	1	15/60	425
Returned Inadmissible Passenger	Contact information collection for public health follow up.	835	1	5/60	70
Airline Representative	Contact information collection for public health follow up.	835	1	10/60	139
Total					352,538,030

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–24994 Filed 11–15–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Intergovernmental Reference Guide (IRG) (OMB No.: 0970–0209)

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), Office of Child Support Enforcement (OCSE), is requesting the Office of Management and Budget (OMB) to approve the Intergovernmental Reference Guide (IRG), with content and organizational revisions, for an additional three years. The IRG contains state and tribal child support information that assists state and tribal child support enforcement (CSE) agencies administering their respective programs. The current OMB approval expires on January 31, 2022.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent directly to the following: *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.

SUPPLEMENTARY INFORMATION:

Description: The IRG is a centralized and automated repository of state and tribal profiles that contains high-level descriptions of each CSE program. These profiles provide state, tribal, and foreign country CSE agencies with an effective and efficient method for updating and accessing information needed to process intergovernmental child support cases. Fourteen comments received after the 60-day **Federal Register** publication and comment period have resulted in revisions to the proposed state profile to clarify the content and amend the organizational format. No comments were received regarding the proposed tribal profile organizational changes.

Respondents: State and Tribal Child Support Enforcement Agencies.

ANNUAL BURDEN ESTIMATES

Information collection instrument	Total number of annual respondents	Number of annual responses per respondent	Average annual burden hour per response	Annual burden hours
IRG: State Profile Guide(states and territories)	54	18	0.3	292
IRG: Tribal Profile Guide	62	18	0.3	335

Estimated Total Annual Burden Hours: 627.

Authority: 42 U.S.C. 652(a)(7); 42 U.S.C. 666(f); 45 CFR 301.1; 45 CFR 303.7; and 45 CFR 309.120.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–24919 Filed 11–15–21; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Head Start Family and Child Experiences Survey (FACES) (OMB #0970–0151)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new wave of the Head Start Family and Child Experiences Survey (FACES) as well as a follow-up to a special data collection fielded in the fall of 2021.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

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.

SUPPLEMENTARY INFORMATION:

Description: The purpose of the FACES data collection is to support the 2007 reauthorization of the Head Start program (Pub. L. 110–134), which calls for periodic assessments of Head Start's quality and effectiveness.

FACES 2019 focuses on Head Start Regions I through X (which are geographically based); AIAN (American Indian and Alaska Native) FACES 2019 focuses on Region XI (which funds Head Start programs that serve federally recognized American Indian and Alaska Native tribes). Both studies will provide data on a set of key indicators for Head Start programs. Information about the Head Start program recruitment and center selection processes and on the fall 2019, spring 2020, and fall 2021 data collection activities for both FACES and AIAN FACES can be found here: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202005-0970-009.*

This 30-day notice describes:

- The spring 2022 round of FACES program- and classroom-level data collection.
- A follow-up in spring 2022 of the fall 2021 FACES and AIAN FACES child-level data collection.

FACES spring 2022 data collection will take place in 180 Head Start programs nationwide. Of the 180 programs, 60 will have participated in fall data collection and 120 will be added to participate in classroom- and program-data collection only. AIAN FACES will continue in the same 22 programs that participated in 2019, 2020, and 2021 data collection. Data collection activities will include teacher sampling (for the 120 FACES programs not part of fall 2021), parent surveys, teacher child reports, staff surveys, and, for FACES, classroom observations.

In the additional 120 programs added to FACES in spring 2022, data collection will begin with sampling of FACES teachers in 240 Head Start centers. Study team members will request a list of all teachers working with Head Start-funded children.

As in fall 2021, for the spring 2022 follow-up data collection, FACES will survey the parents of 2,400 Head Start children in Regions I–X (FACES 2019) and 800 children in Region XI (AIAN FACES 2019) and ask their Head Start teachers to rate children's learning skills and social and emotional skills. Parents of sampled children (2,400 for FACES and 800 for AIAN FACES) will complete surveys on the web or by telephone about their children and family. In all 202 programs (180 for FACES and 22 for AIAN FACES), Head Start teachers will rate each sampled child (approximately 10 children per teacher) using the web or paper-and-pencil forms. Teachers, program directors, and center directors will also complete a survey, also using the web or paper-and-pencil forms, about themselves and the services and instruction at Head Start.

Respondents: Parents of Head Start children; Head Start staff.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total/annual burden (in hours)
FACES 2019 spring 2022 special teacher sampling form from Head Start staff	240	1	.17	41
FACES 2019 special Head Start parent survey	2,400	1	.58	1,392
FACES 2019 special Head Start teacher child report	240	10	.17	408
FACES 2019 Head Start teacher survey	720	1	.67	482
FACES 2019 Head Start center director survey	360	1	.58	209
FACES 2019 Head Start program director survey	180	1	.67	121
AIAN FACES 2019 special Head Start parent survey	800	1	.58	464
AIAN FACES 2019 special Head Start teacher child report	90	9	.17	138
AIAN FACES 2019 Head Start teacher survey	90	1	.58	52
AIAN FACES 2019 Head Start center director survey	42	1	.50	21
AIAN FACES 2019 Head Start program director survey	22	1	.50	11

Estimated Total Annual Burden Hours: 3,339.

Authority: Section 640(a)(2)(D) and section 649 of the Improving Head Start for School Readiness Act of 2007.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–24951 Filed 11–15–21; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; Evidence Based Program Fidelity Surveys [OMB #0985–New]

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to the information collection requirements for the Evidence Based Program Fidelity Surveys [OMB #0985–New].

DATES: Submit written comments on the collection of information by December 16, 2021.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice online at *www.reginfo.gov/public/do/PRAMain.* Find the information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments can also be submitted By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Susan Jenkins, Administration for Community Living, Washington, DC 20201, 202–795–7369 or by email: *Susan.Jenkins@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance.

The Administration for Community Living (ACL) is requesting approval to collect data for the Evidence Based Program Fidelity Surveys [OMB #0985–New]. The Evidence Based Program Fidelity Surveys will be used by ACL to evaluate the fidelity with which ACL's grantee organizations, under the Older Americans Act, implement the required evidence-based programs. States that receive Older Americans Act funds under Title III–D are required to spend those funds on evidence-based programs to improve the health and well-being of their clients and to reduce disease and injury. Since 2003, the aging services network has been steadily moving towards wider implementation of disease prevention and health promotion programs that are based on scientific evidence and demonstrated to improve the health of older adults. The FY 2012 Congressional appropriations law included, for the first time, an evidence-based requirement related to Title III–D funds.

The results of this information collection will be used by ACL/AoA to:

- Effectively report its results to the President, to Congress, to the Department of Health and Human Services and to the public.
- Assess the effectiveness of ACL and its grantees in monitoring program fidelity.
- Aid in program refinement and continuous improvement.

Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register** on, July 12, 2021 in 86 FR 13720. There were 0 public comments received during the 60-day FRN.

Estimated Program Burden:

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Grantee: Program selection process and survey	103	1	2.00	206
Local Implementation Organization Survey	412	1	0.58	239
Total:	515	1	0.86	445

Dated: November 9, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2021–24923 Filed 11–15–21; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1992–N–0011]

Sanyasi Raju Kalidindi; Grant of Special Termination

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has issued an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) granting special termination of the debarment of Sanyasi Raju Kalidindi. FDA based the order on a finding that Dr. Kalidindi provided substantial assistance in the investigations or prosecutions of offenses relating to a matter under FDA's jurisdiction and that terminating Dr. Kalidindi's debarment served the interest of justice and protected the integrity of the drug approval process.

DATES: The order became effective September 15, 2021.

ADDRESSES: Comments should reference Docket No. FDA–1992–N–0011 and be sent to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Karena Cooper, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4218, Silver Spring, MD 20993, 301 796–1612.

SUPPLEMENTARY INFORMATION: In a **Federal Register** notice dated April 21, 1993 (58 FR 21470), FDA debarred Dr. Kalidindi from providing services in any capacity to a person with an approved or pending drug product

application under section 306(a) of the FD&C Act (21 U.S.C. 335a(a)). FDA based the debarment on a finding under section 306(a)(2) of the FD&C Act that Dr. Kalidindi had been convicted of a felony under Federal law for conduct relating to the development, or approval, of any drug product or otherwise relating to the regulation of a drug product.

Section 306(d)(4) of the FD&C Act provides that any individual debarred under section 306(a)(2) may apply to FDA for special termination of debarment. Pursuant to section 306(d)(4)(C)–(D), FDA may grant a request for special termination and limit the period of debarment to less than permanent but no less than 1 year if the Agency finds: (1) That the individual has provided substantial assistance in the investigations or prosecutions of offenses described in section 306(a) or (b) of the FD&C Act, or relating to any matter under the jurisdiction of FDA and (2) that doing so best serves the interest of justice and protects the integrity of the drug approval process.

On May 27, 1998, FDA denied a previous petition for special termination of debarment submitted by Dr. Kalidindi. On January 13, 2020, Dr. Kalidindi again petitioned for special termination of debarment under section 306(d)(4) of the FD&C Act. On April 10, 2020, FDA's Office of Regulatory Affairs proposed denying that petition and offered Dr. Kalidindi an opportunity to request a hearing on the proposal to deny the petition. On May 9, 2020, Dr. Kalidindi requested a hearing and, on June 8, 2020, submitted materials in support of his hearing request.

By a decision dated September 15, 2021, FDA's Chief Scientist granted Dr. Kalidindi's petition for special termination based on her conclusion that doing so best served the interest of justice and protected the integrity of the drug approval process. In so concluding, she found that there were no genuine and substantial issues of fact with respect to the level and scope of substantial assistance provided by Dr. Kalidindi in the investigation and prosecution of others for offenses described in section 306(a) or (b) of the FD&C Act, or otherwise relating to FDA's jurisdiction, and that the level and scope of such substantial assistance, among other considerations, justified special termination of his debarment after 28 years. The Chief Scientist's decision is available at *https://www.fda.gov/media/152270/download.* The decision is also available at *https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/fda-debarment-list-drug-product-applications/fda-expired-debarment-list-drug-product-applications.*

Dated: November 4, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24973 Filed 11–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–2167 and FDA–2020–E–2168]

Determination of Regulatory Review Period for Purposes of Patent Extension; QINLOCK

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for QINLOCK and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 18, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 16, 2022. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 18, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 18, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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 Nos. FDA–2020–E–2167 and FDA–2020–E–2168 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; QINLOCK.'' 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 § 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, QINLOCK (ripretinib) indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor who have received prior treatment with 3 or more kinase inhibitors, including imatinib. Subsequent to this approval, the USPTO received patent term restoration applications for QINLOCK (U.S. Patent Nos. 8,188,113 and 8,461,179) from Deciphera Pharmaceuticals LLC and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated December 14, 2020, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of QINLOCK represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for QINLOCK is 1,741 days. Of this time, 1,586 days occurred during the testing phase of the regulatory review period, while 155 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* August 11, 2015. FDA has verified the applicant's claims that the date the investigational new drug application became effective was on August 11, 2015.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 13, 2019. FDA has verified the applicant's claims that the new drug application (NDA) for QINLOCK (NDA 213973) was initially submitted on December 13, 2019.

3. *The date the application was approved:* May 15, 2020. FDA has verified the applicant's claims that NDA 213973 was approved on May 15, 2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 707 days or 947 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket Nos. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 3, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24978 Filed 11–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Ryan White HIV/AIDS Program Client-Level Data Reporting System, OMB No. 0906–0039—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA is submitting an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than December 16, 2021.

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 Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the acting HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Ryan White HIV/AIDS Program Client-Level Data Reporting System, OMB No. 0906–0039—Extension.

Abstract: The Ryan White HIV/AIDS Program (RWHAP), authorized under Title XXVI of the Public Health Service Act, is administered by the HIV/AIDS Bureau within HRSA. HRSA awards funding to recipients in areas of the greatest need to respond effectively to the changing HIV epidemic, with an emphasis on providing life-saving and life-extending medical care, treatment and support services for people living with HIV in the United States.

The RWHAP reporting requirements include the annual submission of client-level data in the Ryan White HIV/AIDS Program Services Report (RSR). The RSR is designed to collect information from grant recipients and their subcontracted service providers, funded under Parts A, B, C, and D of the RWHAP legislation. HRSA is requesting an extension of the current RSR with no changes.

A 60-day notice published in the **Federal Register**, 86 FR 44376 (August 12, 2021). There were were no public comments.

Need and Proposed Use of the Information: The RWHAP legislation specifies HRSA's responsibilities in administering grant funds, allocating funding, assessing HIV care outcomes (*e.g.,* viral suppression), and serving particular populations. The RSR collects data on the characteristics of RWHAP-funded recipients, their contracted service providers, and the patients or clients served. The RSR system consists of two primary components, the Recipient Report and the Provider Report, and a data file containing the client-level data elements. Data are submitted annually. The RWHAP legislation specifies the importance of recipient accountability and linking performance to budget. The RSR is used to ensure recipient compliance with the law, including evaluating the effectiveness of programs, monitoring recipient and provider performance, and informing annual reports to Congress. Information collected through the RSR is critical for HRSA, state and local grant recipients, and individual providers to assess the status of existing HIV-related service delivery systems, assess trends in service utilization, assess the impact of data reporting and identify areas of greatest need.

Likely Respondents: RWHAP grant recipients, as well as their subcontracted service providers, funded under RWHAP Parts A, B, C, and D.

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
Recipient Report	595	1	595	11	6,545
Provider Report	2,063	1	2,063	13	26,819
Client Report	1,532	1	1,532	113	173,116
Total	4,190	.....	4,190	.....	206,480

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. 2021–24922 Filed 11–15–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Blood and Tissue Safety and Availability

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services is hereby giving notice that the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) will hold a virtual meeting. The meeting will be open to the public. For this meeting, the committee will discuss and vote on a recommendation pertaining to a proposed update to the 2020 Public Health Service (PHS) Guideline for Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection. The following question will be posed to the committee: Does the available data support exempting solid organ transplant candidates who are ≤10 years of age at the time of transplant (and who have received postnatal infectious disease testing) from the recommendation for HIV, Hepatitis B virus, and Hepatitis C virus testing during the hospital admission for transplant but prior to anastomosis of the first organ?

DATES: The meeting will take place virtually on Wednesday, December 1, 2021 from approximately 11:00 a.m.–3:00 p.m. Eastern Time (ET). Meeting times are tentative and subject to change. The confirmed times and agenda items for the meeting will be posted on the ACBTSA web page at *https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meetings/2021-12-01/index.html* when this information becomes available.

FOR FURTHER INFORMATION CONTACT: James Berger, Designated Federal Officer for the ACBTSA; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L600, Washington, DC 20024. (202) 795–7608 or Email: *ACBTSA@hhs.gov.*

SUPPLEMENTARY INFORMATION: The ACBTSA is a discretionary Federal advisory committee. The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees. On the day of the meeting, please go to *https://www.hhs.gov/live/index.html* to view the meeting. The public will have an opportunity to present their views to the ACBTSA by submitting a written public comment. Comments should be pertinent to the meeting discussion. Persons who wish to provide written public comment should review instructions at *https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meetings/2021-12-01/index.html* and respond by midnight November 26, 2021, ET. Written public comments will be accessible to the public on the ACBTSA web page prior to the meeting.

ACBTSA functions to provide advice to the Secretary through the Assistant Secretary for Health on a range of policy issues to include: (1) Identification of public health issues through surveillance of blood and tissue safety issues with national survey and data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical, and legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors (*e.g.,* product cost and supply) on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues. The Committee has met regularly since its establishment in 1997.

Dated: October 27, 2021.

James J. Berger,

Designated Federal Officer, Advisory Committee on Blood and Tissue Safety and Availability, Office of Infectious Disease and HIV/AIDS Policy.

[FR Doc. 2021–24895 Filed 11–15–21; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Division of Extramural Research and Training (DERT) Extramural Grantee Data Collection (National Institute of Environmental Health Sciences)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

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: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Kristianna Pettibone, Evaluator, Program Analysis Branch, NIEHS, NIH, 530 Davis Dr., Room 3064, Morrisville, NC 20560, or call non-toll-free number 984–287–3303 or Email your request, including your address to: *pettibonekg@niehs.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on September 13, 2021, Volume 86, Number 74, page 50897–50898 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: DERT Extramural Grantee Data Collection, 0925–0757– REVISION—Expiration Date 11/30/2021, National Institute of Environmental Health Sciences

(NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: In order to make informed management decisions about its research programs and to demonstrate the outputs, outcomes and impacts of its research programs NIEHS will collect, analyze and report on data from extramural grantees who are currently receiving funding or who have received funding in the past on topics such as: (1) Key scientific outcomes achieved through the research and the impact on the field of environmental health science; (2) Contribution of research findings to program goals and objectives; (3) Satisfaction with the program support received; (4) Challenges and benefits of the funding mechanism used to support the science; and (5) Emerging research areas and gaps in the research.

Information gained from this primary data collection will be used in conjunction with data from grantee progress reports and presentations at grantee meetings to inform internal programs and new funding initiatives.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 740.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
NICHD Grantee	200	1	30/60	100
NIDCD Grantee	200	1	30/60	100
NIMH Grantee	200	1	30/60	100
NINDS Grantee	200	1	30/60	100
NCI Grantee	400	1	30/60	200
NIEHS Grantee (long form)	200	1	30/60	100
NIEHS Grantee (short form)	240	1	10/60	40
Total		1,640		740

Jane M. Lambert,

Project Clearance Liaison, National Institute of Environmental Health Sciences, National Institutes of Health.

[FR Doc. 2021–24920 Filed 11–15–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Nephrology and Hemodialysis Small Business Activities.

Date: November 23, 2021.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Santanu Banerjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2106, Bethesda, MD 20892, (301) 435–5947, *banerjees5@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 10, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24997 Filed 11–15–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Research Education Program (R25 Clinical Trial Not Allowed).

Date: December 10, 2021.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health,5601 Fishers Lane, Room 3G21, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Robert C. Unfer, Ph.D., Scientific Review Officer, Scientific Review Program,Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health,5601 Fishers Lane, Room 3G21, Rockville, MD 20852, (240) 669–5035,*robert.unfer@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 9, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24938 Filed 11–15–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR: Electronic Nicotine Delivery Systems: Basic Mechanisms of Health Effects.

Date: December 14–15, 2021.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bradley Nuss, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC7814, Bethesda, MD 20892, 301–451–8754, *nussb@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR: 20–181 Limited Competition National Primate Research Program Projects.

Date: December 15–17, 2021.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, EMNR IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6182, MSC 7892, Bethesda, MD 20892, 301–435–2514, *riverase@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 10, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24995 Filed 11–15–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2010–1066]

Recreational Boating Safety Projects, Programs, and Activities Funded Under Provisions of the Fixing America's Surface Transportation Act; Fiscal Year 2021

ACTION: Notice.

SUMMARY: The Coast Guard is publishing this notice to satisfy a requirement of the Fixing America's Surface Transportation Act that requires a detailed accounting of the projects, programs, and activities funded under the national recreational boating safety program provision of the Act be published annually in the **Federal Register**. This notice specifies the funding amounts the Coast Guard has committed, obligated, or expended during fiscal year 2021, as of September 30, 2021.

FOR FURTHER INFORMATION CONTACT: For questions on this notice please contact Mr. Jeff Decker, U.S. Coast Guard, Regulations Development Manager, (202) 372–1507 or mail to: *RBSInfo@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

Since 1998, Congress has passed a series of laws providing funding for projects, programs, and activities funded under the national recreational boating safety program, which is administered by the U.S. Coast Guard. For a detailed description of the legislative history, please see the Recreational Boating Safety Projects, Programs, and Activities Funded Under Provisions of the Fixing America's Surface Transportation Act; Fiscal Year 2020 Notice published in the **Federal Register** on November 23, 2020 (85 FR 74741).

These funds are available to the Secretary from the Sport Fish Restoration and Boating Trust Fund (Trust Fund) established under 26 U.S.C. 9504(a) for payment of Coast Guard expenses for personnel and activities directly related to coordinating and carrying out the national recreational boating safety program. Amounts made available under this subsection remain available during the two succeeding fiscal years. Any amount that is unexpended or unobligated at the end of the three-year period during which it is available shall be withdrawn by the Secretary and allocated to the States in addition to any other amounts available for allocation in the fiscal year in which they are withdrawn or the following fiscal year.

Use of these funds requires compliance with standard Federal contracting rules with associated lead and processing times resulting in a lag time between available funds and spending. The total amount of funding transferred to the Coast Guard from the Trust Fund, and committed, obligated, and/or expended during fiscal year 2021 for each project is shown below.

Specific Accounting of Funds

The total amount of funding transferred to the Coast Guard from the Sport Fish Restoration and Boating Trust Fund and committed, obligated, and/or expended during fiscal year 2021 for each project is shown in the chart below.

Project	Description	Cost
46 USC 43 Compliance: Inspection Program/Boat Testing Program.	Provided for continuance of the national recreational boat compliance inspection program, which began in January 2001.	$3,888,425
46 USC 43 Compliance: Staff Salaries	Provided for personnel to oversee manufacturer compliance with 46 USC 43 requirements.	543,742
46 USC 43 Compliance: ..... Staff Travel	Provided for travel by employees of the Boating Safety Division to oversee manufacturer compliance with 46 USC 43 requirements.	26,274
Administrative Overhead	Supplies and Materials to support the RBS Program	298,965

Project	Description	Cost
Boating Accident Report Database (BARD) Web System.	Provided for maintaining the BARD Web System, which enables reporting authorities in the 50 States, five U.S. Territories, and the District of Columbia to submit their accident reports electronically over a secure Internet connection.	363,970
National Boating Safety Advisory Council	Provided for travel performed by NBSAC members, meeting room costs and administrative costs to support the NBSAC.	203
Contract Personnel Support	Provided contract personnel to conduct boating safety-related research and analysis.	730,822
Grant Management Training	Provided to facilitate staff training on new grant management requirements	159,421
Recreational Boating Safety Program Travel.	Provided for travel by employees of the Boating Safety Division to gather background and planning information for new recreational boating safety initiatives.	46,092
Reimbursable Salaries	Provided for 18 personnel directly related to coordinating and carrying out the national recreational boating safety program.	2,943,134

Of the $8.423 million made available to the Coast Guard in fiscal year 2021, $100,000 has been committed, obligated, or expended and an additional $8,901,048 of prior fiscal year funds have been committed, obligated, or expended, as of September 30, 2021. The remainder of the FY20 and FY21 funds made available to the Coast Guard (approximately $9.012 million) may be retained for the allowable period for the National Recreational Boating Survey, the expected reengineering of the Boating Accident and Reporting Database, and other projects, or it may be transferred into the pool of money available for allocation through the state grant program.

Authority: This notice is issued pursuant to 5 U.S.C. 552 and 46 U.S.C. 13107(c)(4).

Dated: November 9, 2021.

Wayne R. Arguin, Jr.,

Captain, U.S. Coast Guard, Director of Inspections and Compliance.

[FR Doc. 2021–24934 Filed 11–15–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *https://msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Colorado: Boulder (FEMA Docket No.: B–2153).	City of Longmont (20–08–0847P).	The Honorable Brian Bagley, Mayor, City of Longmont, 350 Kimbark Street, Longmont, CO 80501.	Development Services Center, 385 Kimbark Street, Longmont, CO 80501.	Oct. 25, 2021	080027
Florida:					
Alachua (FEMA Docket No.: B–2153).	Unincorporated areas of Alachua County (21–04–0749P).	Ms. Michelle L. Lieberman, Alachua County Manager, 12 Southeast 1st Street, Gainesville, FL 32601.	Alachua County Public Works Department, 5620 Northwest 120th Lane, Gainesville, FL 32653.	Oct. 20, 2021	120001
Charlotte (FEMA Docket No.: B–2148).	Unincorporated areas of Charlotte County (21–04–2201P).	The Honorable Bill Truex, Chairman, Charlotte County Board of Commissioners, 18500 Murdock Circle, Suite 536, Port Charlotte, FL 33948.	Charlotte County Community Development Department, 18500 Murdock Circle Port, Charlotte, FL 33948.	Oct. 13, 2021	120061
Duval (FEMA Docket No.: B–2159).	City of Jacksonville (21–04–0882P).	The Honorable Lenny Curry, Mayor, City of Jacksonville, 117 West Duval Street, Suite 400, Jacksonville, FL 32202.	Development Services Division, 214 North Hogan Street, Jacksonville, FL 32202.	Oct. 25, 2021	120077
Glades (FEMA Docket No.: B–2159).	Seminole Tribe of Florida (21–04–1236P).	The Honorable Marcellus W. Osceola, Jr., Chairman, Seminole Tribe of Florida, 6300 Stirling Road, Hollywood, FL 33024.	Hollywood Environmental Resource Management Department, 6363 Taft Street, Suite 309, Hollywood, FL 33024.	Oct. 21, 2021	120685
Glades (FEMA Docket No.: B–2159).	Unincorporated areas of Glades County (21–04–1236P).	The Honorable Tim Stanley, Chairman, Glades County Board of Commissioners, P.O. Box 1527, Moore Haven, FL 33471.	Glades County Community Development Department, 198 6th Street, Moore Haven, FL 33471.	Oct. 21, 2021	120095
Hendry (FEMA Docket No.: B–2159).	Seminole Tribe of Florida (19–04–1505P).	The Honorable Marcellus W. Osceola, Jr., Chairman, Seminole Tribe of Florida, 6300 Stirling Road, Hollywood, FL 33024.	Hollywood Environmental Resource Management Department, 6363 Taft Street, Suite 309, Hollywood, FL 33024.	Oct. 15, 2021	120685
Hendry (FEMA Docket No.: B–2159).	Unincorporated areas of Hendry County (19–04–1505P).	The Honorable Mitchell Wills, Chairman, Hendry County Board of Commissioners, P.O. Box 2340, LaBelle, FL 33975.	Hendry County Building Department, 640 South Main Street, LaBelle, FL 33935.	Oct. 15, 2021	120107
Lee (FEMA Docket No.: B–2153).	Unincorporated areas of Lee County (21–04–1477P).	Mr. Roger Desjarlais, Lee County Manager, 2115 2nd Street, Fort Myers, FL 33901.	Lee County Building Department, 1500 Monroe Street, Fort Myers, FL 33901.	Oct. 20, 2021	125124
Lee (FEMA Docket No.: B–2153).	Village of Estero (21–04–1477P).	Mr. Steven R. Sarkozy, Village of Estero Manager, 9401 Corkscrew Palms Circle, Estero, FL 33928.	Village Hall, 9401 Corkscrew Palms Circle, Estero, FL 33928.	Oct. 20, 2021	120260
Monroe (FEMA Docket No.: B–2153).	Village of Islamorada (21–04–2470P).	The Honorable Buddy Pinder, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Building Department, 86800 Overseas Highway, Islamorada, FL 33036.	Oct. 18, 2021	120424
Palm Beach (FEMA Docket No.: B–2153).	Unincorporated areas of Palm Beach County (20–04–0988P).	Ms. Verdenia C. Baker, Palm Beach County Administrator, 301 North Olive Avenue, Suite 1101 West Palm Beach, FL 33401.	Palm Beach County Planning, Zoning and Building Department, 2300 North Jog Road, Room 1E–17, West Palm Beach, FL 33411.	Oct. 18, 2021	120192
Sarasota (FEMA Docket No.: B–2153).	Unincorporated areas of Sarasota County (21–04–1410P).	The Honorable Alan Maio, Chairman, Sarasota County Board of Commissioners, 1660 Ringling Boulevard, Sarasota, FL 34236.	Sarasota County Planning and Development, Services Department, 1001 Sarasota Center Boulevard, Sarasota, FL 34240.	Oct. 13, 2021	125144
Sumter (FEMA Docket No.: B–2153).	City of Wildwood (20–04–3503P).	The Honorable Ed Wolf, Mayor, City of Wildwood, 100 North Main Street Wildwood, FL 34785.	Public Works Department, 743 Huey Street, Wildwood, FL 34785.	Oct. 15, 2021	120299
Sumter (FEMA Docket No.: B–2153).	City of Wildwood (20–04–3653P).	The Honorable Ed Wolf, Mayor, City of Wildwood, 100 North Main Street, Wildwood, FL 34785.	Public Works Department, 743 Huey Street, Wildwood, FL 34785.	Oct. 15, 2021	120299
Sumter (FEMA Docket No.: B–2153).	Unincorporated areas of Sumter County (20–04–3503P).	The Honorable Garry Breeden, Chairman, Sumter County Board of Commissioners, 7375 Powell Road Wildwood, FL 34785.	Sumter County Planning Department 7375 Powell Road, Suite 115 Wildwood, FL 34785.	Oct. 15, 2021	120296
Sumter (FEMA Docket No.: B–2153).	Unincorporated areas of Sumter County (20–04–3653P).	The Honorable Garry Breeden, Chairman, Sumter County Board of Commissioners, 7375 Powell Road, Wildwood, FL 34785.	Sumter County Planning Department, 7375 Powell Road, Suite 115, Wildwood, FL 34785.	Oct. 15, 2021	120296
Walton (FEMA Docket No.: B–2159).	City of Freeport (21–04–1423P).	The Honorable Russ Barley, Mayor, City of Freeport, 112 State Highway 20 West, Freeport, FL 32439.	Planning and Zoning Department, 16040 Highway 331 Business, Freeport, FL 32439.	Oct. 18, 2021	120319
Kentucky: Hardin (FEMA Docket No.: B–2153).	City of Vine Grove (21–04–0296P).	The Honorable Pam Ogden, Mayor, City of Vine Grove, 300 West Main Street, Vine Grove, KY 40175.	City Hall, 300 West Main Street, Vine Grove, KY 40175.	Oct. 25, 2021	210096
Maine: York (FEMA Docket No.: B–2159).	Town of Kittery (20–01–0605P).	Ms. Kendra Amaral, Manager, Town of Kittery, 200 Rogers Road, Kittery, ME 03904.	Planning and Development Department, 200 Rogers Road, Kittery, ME 03904.	Oct. 14, 2021	230171
New Mexico: Bernalillo (FEMA Docket No.: B–2148).	Unincorporated areas of Bernalillo County (20–06–2872P).	The Honorable Charlene E. Pyskoty, Chair, Bernalillo County Board of Commissioners, 1 Civic Plaza Northwest, Albuquerque, NM 87102.	Bernalillo County Public Works Department, 2400 Broadway Boulevard, Albuquerque, NM 87102.	Oct. 12, 2021	350001
Pennsylvania:					
Lackawanna (FEMA Docket No.: B–2148).	Borough of Moosic (21–03–0726P).	The Honorable James Segilia, Mayor, Borough of Moosic, 715 Main Street, Moosic, PA 18507.	Borough Hall, 715 Main Street, Moosic, PA 18507.	Oct. 18, 2021	420533
Lackawanna (FEMA Docket No.: B–2148).	Borough of Old Forge (21–03–0726P).	The Honorable Bob Legg, Mayor, Borough of Old Forge, 310 South Main Street, Old Forge, PA 18518.	Borough Hall, 310 South Main Street, Old Forge, PA 18518.	Oct. 18, 2021	420535
Texas:					

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Bexar (FEMA Docket No.: B–2159).	City of San Antonio (20–06–2739P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvement, Storm Water Division, 114 West Commerce Street, San Antonio, TX 78205.	Oct. 18, 2021	480045
Bexar (FEMA Docket No.: B–2159).	City of San Antonio (21–06–0439P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvement, Storm Water Division, 114 West Commerce Street, San Antonio, TX 78205.	Oct. 25, 2021	480045
Bexar (FEMA Docket No.: B–2159).	Unincorporated areas of Bexar County (21–06–0439P).	The Honorable Nelson W. Wolff, Bexar County Judge, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 1948 Probandt Street, San Antonio, TX 78214.	Oct. 25, 2021	480035
Collin (FEMA Docket No.: B–2153).	City of McKinney (21–06–0619P).	The Honorable George Fuller, Mayor, City of McKinney, P.O. Box 517, McKinney, TX 75070.	Engineering Department, 221 North Tennessee Street, McKinney, TX 75069.	Oct. 12, 2021	480135
Collin (FEMA Docket No.: B–2153).	Unincorporated areas of Collin County (21–06–0619P).	The Honorable Chris Hill, Collin County Judge, 2300 Bloomdale Road, Suite 4192, McKinney, TX 75071.	Collin County Engineering Department, 4690 Community Avenue, Suite 200, McKinney, TX 75071.	Oct. 12, 2021	480130
Dallas (FEMA Docket No.: B–2153).	City of Rowlett (21–06–0711P).	The Honorable Tammy Dana-Bashian, Mayor, City of Rowlett, 4000 Main Street, Rowlett, TX 75088.	Community Development Department, 5702 Rowlett Road, Rowlett, TX 75089.	Oct. 15, 2021	480185
Dallas (FEMA Docket No.: B–2148).	Town of Sunnyvale (20–06–3713P).	The Honorable Saji George, Mayor, Town of Sunnyvale, 127 North Collins Road Sunnyvale, TX 75182.	Town Hall, 127 North Collins Road Sunnyvale, TX 75182.	Oct. 18, 2021	480188
Galveston (FEMA Docket No.: B–2159).	City of League City (21–06–0710P).	The Honorable Pat Hallisey, Mayor, City of League City, 300 West Walker Street, League City, TX 77573.	Engineering Department, 500 West Walker Street, League City, TX 77573.	Oct. 18, 2021	485488
Galveston (FEMA Docket No.: B–2159).	Unincorporated areas of Galveston County (21–06–0710P).	The Honorable Mark Henry, Galveston County Judge, 772 Moody Avenue, Suite 200, Galveston, TX 77550.	Galveston County Building Department, 823 Rosenberg Street, Galveston, TX 77553.	Oct. 18, 2021	485470
Webb (FEMA Docket No.: B–2159).	Unincorporated areas of Webb County (21–06–0214P).	The Honorable Tano E. Tijerina, Webb County Judge, 1000 Houston Street, 3rd Floor, Laredo, TX 78040.	Webb County Planning Department, 1110 Washington Street, Suite 302, Laredo, TX 78040.	Oct. 12, 2021	481059
Williamson (FEMA Docket No.: B–2153).	City of Georgetown (21–06–0115P).	Mr. David Morgan, Manager, City of Georgetown, P.O. Box 409, Georgetown, TX 78626.	Mapping and GIS Department, 300–1 Industrial Avenue, Georgetown, TX 78626.	Oct. 14, 2021	480668
Williamson (FEMA Docket No.: B–2153).	Unincorporated areas of Williamson County (21–06–0115P).	The Honorable Bill Gravell, Jr., Williamson County Judge, 710 South Main Street, Suite 101, Georgetown, TX 78626.	Williamson County Engineering Department, 3151 Southeast Inner Loop, Georgetown, TX 78626.	Oct. 14, 2021	481079
Utah: Washington (FEMA Docket No.: B–2153).	City of Hurricane (20–08–1034P).	The Honorable John W. Bramall, Mayor, City of Hurricane, 147 North 870 West, Hurricane, UT 84737.	Engineering Department, 147 North 870 West, Hurricane, UT 84737.	Oct. 25, 2021	490172

[FR Doc. 2021–24983 Filed 11–15–21; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002; Internal Agency Docket No. FEMA–B–2177]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: Comments are to be submitted on or before February 14, 2022.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2177, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security,Federal Emergency Management Agency.

Community	Community map repository address
Chilton County, Alabama and Incorporated Areas Project: 18–04–0029S Preliminary Date: May 8, 2020	
City of Calera	Engineering Department, 1074 10th Street, Calera, AL 35040.
City of Clanton	Building Department, 505 2nd Avenue North, Room 225, Clanton, AL 35045.
City of Jemison	City Hall, 14 Padgett Lane, Jemison, AL 35085.
Town of Thorsby	Town Hall, 21060 U.S. Highway 31, Thorsby, AL 35171.
Unincorporated Areas of Chilton County	Chilton County Road Department, 272 Airport Lane, Clanton, AL 35045.
Clay County, Alabama and Incorporated Areas Project: 18–04–0029S Preliminary Date: May 8, 2020	
Unincorporated Areas of Clay County	Clay County Engineering Department, 86842 Alabama Highway 9, Lineville, AL 36266.
Coosa County, Alabama and Incorporated Areas Project: 18–04–0029S Preliminary Date: May 8, 2020	
Town of Goodwater	City Hall, 22132 Alabama Highway 9, Goodwater, AL 35072.
Town of Rockford	Town Hall, 9688 U.S Highway 231, Rockford, AL 35136.
Unincorporated Areas of Coosa County	Coosa County Courthouse, 9709 U.S. Highway 231, Rockford, AL 35136.
Elmore County, Alabama and Incorporated Areas Project: 18–04–0029S Preliminary Date: May 8, 2020	
City of Wetumpka	City Hall, 408 South Main Street, Wetumpka, AL 36092.
Town of Elmore	Town Hall, 485 Jackson Street, Elmore, AL 36025.
Unincorporated Areas of Elmore County	Elmore County Highway Department, 155 County Shop Road, Wetumpka, AL 36092.
Shelby County, Alabama and Incorporated Areas Project: 18–04–0029S Preliminary Date: May 8, 2020	
City of Alabaster	City Hall, 1953 Municipal Way, Alabaster, AL 35007.
City of Chelsea	City Hall, 11611 Chelsea Road, Chelsea, AL 35043.
City of Columbiana	City Hall, 107 Mildred Street, Columbiana, AL 35051.
Town of Harpersville	Town Hall, 83 Town Hall Lane, Harpersville, AL 35078.
Town of Westover	Town Hall, 3312 Westover Road, Westover, AL 35147.
Town of Wilsonville	Town Hall, 9905 North Main Street, Wilsonville, AL 35186.
Unincorporated Areas of Shelby County	Shelby County Highway Department, 506 Alabama Highway 70, 2nd Floor, Columbiana, AL 35051.

Community	Community map repository address
Talladega County, Alabama and Incorporated Areas Project: 18–04–0029S Preliminary Date: May 8, 2020	
City of Childersburg	City Hall, 201 8th Avenue Southwest, Childersburg, AL 35044.
City of Sylacauga	City Hall, 301 North Broadway Avenue, Sylacauga, AL 35150.
Town of Bon Air	Town Office, 227 Front Street, Bon Air, AL 35032.
Unincorporated Areas of Talladega County	Talladega County Highway Department, 820 Alabama Highway 275, Talladega, AL 35160.
Henderson, Kentucky and Incorporated Areas Project: 16–04–8581S Preliminary Date: May 26, 2021	
City of Henderson	City Hall, 222 1st Street, Henderson, KY 42420.
City of Robards	City Hall, 1101 Clark Street, Robards, KY 42452.
Unincorporated Areas of Henderson County	Henderson City-County Planning Commission, 1990 Barrett Court, Suite C, Henderson, KY 42420.
Union County, Kentucky and Incorporated Areas Project: 16–04–8581S Preliminary Date: May 26, 2021	
City of Morganfield	Union County Courthouse, 100 West Main Street, Morganfield, KY 42437.
City of Uniontown	Union County Courthouse, 100 West Main Street, Morganfield, KY 42437.
Unincorporated Areas of Union County	Union County Courthouse, 100 West Main Street, Morganfield, KY 42437.
Webster County, Kentucky and Incorporated Areas Project: 16–04–8581S Preliminary Date: May 26, 2021	
Unincorporated Areas of Webster County	Webster County Tax Commission Office, 25 U.S. Highway 41–A South, Dixon, KY 42409.
Bexar County, Texas and Incorporated Areas Project: 20–06–0108S Preliminary Date: June 30, 2021	
City of China Grove	City Hall, 2412 FM 1516 South, China Grove, TX 78263.
City of Elmendorf	City Hall, 8304 FM 327, Elmendorf, TX 78112.
City of San Antonio	Transportation and Capital Improvements Department, Storm Water Division, 114 West Commerce Street, 6th Floor, San Antonio, TX 78205.
Unincorporated Areas of Bexar County	Bexar County Public Works Department, 1948 Probandt Street, San Antonio, TX 78214.
Wilson County, Texas and Incorporated Areas Project: 20–06–0107S Preliminary Date: June 30, 2021	
City of Elmendorf	City Hall, 8304 FM 327, Elmendorf, TX 78112.
Unincorporated Areas of Wilson County	Wilson County Courthouse, 1420 3rd Street, Suite 101, Floresville, TX 78114.

[FR Doc. 2021–24982 Filed 11–15–21; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

[Docket Number–DHS–2021–0050]

Agency Information Collection Activities: Family Reunification Task Force Travel Questionnaire and Website Application

AGENCY: Department of Homeland Security (DHS).

ACTION: 60-Day notice and request for comments; Family Reunification Task Force Travel Questionnaire and website Application, extension without change.

SUMMARY: The Department of Homeland Security, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted until December 16, 2021. This process is conducted in accordance with 5 CFR 1320.1.

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 specific information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: On February 2, 2021, President Biden signed Executive Order 14011 (E.O. 14011), Establishment of Interagency Task Force on the Reunification of Families, in response to the prior Administration decision to intentionally separate children from their parents and legal guardians (families), including through the use of the Zero-Tolerance Policy. E.O. 14011 directs the Interagency Task Force on the Reunification of Families (Task Force) to identify children who were separated and facilitate and enable the reunification of the families. Additionally, E.O. 14011 directs the

Task Force to provide recommendations on providing additional services and support for the reunified families, including behavioral health services with a focus on trauma-informed care. The Secretary of Homeland Security is the chair of the Task Force and is joined by the Department of State, Department of Health and Human Services, and the Department of Justice.

To carry out the Task Force's mission to reunify families, DHS is extending the current information data collection. The purpose is to achieve efficiencies to process these individuals for a successful family reunification. To streamline the initial contact, assistance, and reunification travel coordination process, the Task Force has created a website application (Register | *together.gov* and Regístrese | *together.gov* (*juntos.gov*)) to create initial contact and a travel form to collect details and information the Task Force needs to make travel arrangements for the beneficiary and other traveling family members.

The information to be collected on the website application would include:

- A-Number
- Name of Separated Parent
- Contact Information of the Separated Parent (phone, email)
- Country of Birth
- Country of Citizenship
- Current Country Location
- Separated Parent Relationship to Child
- Separated Parent's Preferred Language
- Separated Child's A#
- Separated Child Name
- Separated Child's Date of Birth
- Separated Child's Country of Birth
- Separated Child's Country of Citizenship
- Whether Separated Parent is in contact with Child
- Whether Separated Parent has knowledge of Child's current location
- Name of Attorney, Advocate or Preparer
- Attorney, Advocate, or Preparer Contact Information

The information to be collected for travel would include: Name, Date of Birth, Gender, A#, Passport Number and Expiration, Phone Number, Email address, Language(s) spoken, Representative/Attorney name and contact information, Date of Embassy Appointment to obtain boarding foil, Identification of Special Assistance Requests, Departure Airport, Final Airport, Traveling requested time frame, Names of others in the traveling party. The data will be stored by the international organization coordinating travel for the families.

This information collection does not have an impact on small businesses or other small entities.

If this information is not collected, the Task Force will not be able to accomplish its mission to reunite families swiftly.

The assurance of confidentiality provided to the respondents for this information collection is based on the Privacy Impact Assessment DHS/ALL/PIA–091. The Systems of Records Notices that will be included in this ICR include DHS/USCIS/ICE/CBP–001 Alien File, Index, and National File Tracking System of Records, September 18, 2017, 82 FR 43556 DHS/USCIS–007 Benefits Information System, October 10, 2019, 84 FR 54622.

This information collection was constructed in compliance with regulations and authorities under the purview of the DHS Privacy Office, DHS OCIO, DHS Records Management, and OMB regulations regarding data collection, use, sharing, storage, information security, and retrieval of information.

There are no changes to the information being collected and there is no change to the estimated burden associated with this collection.

The Office of Management and Budget is particularly interested in comments which:

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 estimate 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 submissions of responses.

Analysis

Agency: Department of Homeland Security (DHS).

Title: Family Reunification Task Force Travel Questionnaire and Website Application.

OMB Number: 1601–0031.

Frequency: Annually.

Affected Public: Members of the Public.

Number of Respondents: 3,000.

Estimated Time per Respondent: 20 minutes.

Total Burden Hours: 1,000.

Robert Dorr,

Executive Director, Business Management Directorate.

[FR Doc. 2021–24940 Filed 11–15–21; 8:45 am]

BILLING CODE 9112–FL–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7046–N–07]

Privacy Act of 1974; System of Records

AGENCY: Office of Chief Human Capital Officer, HUD.

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Housing and Urban Development (HUD), Office of the Chief Human Capital Officer (OCHCO) is issuing a public notice of its intent to establish a Privacy Act system of records titled ''HR Case Management Solution,'' HUD/OCHCO 01.

The purpose of this system of records is to allow HUD to collect and maintain records on individuals requesting or receiving reasonable accommodations and religious/medical exception requests.

DATES: This notice shall be applicable immediately, which will become effective December 16, 2021.

Comments will be accepted on or before December 16, 2021. This proposed action will be effective on the date following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number HUD–2021–Docket Number not yet identified.

Federal e-Rulemaking Portal: http://www.regulations.gov. Follow the instructions provided on that site to submit comments electronically.

Fax: 202–619–8365.

Email: www.privacy@hud.gov.

Mail: Attention: Privacy Office; LaDonne White, Chief Privacy Officer; The Executive Secretariat; 451 Seventh Street SW, Room 10139, Washington, DC 20410–0001.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://*

www.regulations.gov. including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ladonne White, Departmental Privacy Officer, 451 Seventh Street SW, Room 10139, Washington, DC 20410–0001, telephone number 202–402–3559 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act of 1974, the Department of Housing and Urban Development (HUD) proposes to establish a new system of records titled, ''HR Case Management Solution.'' This system of records covers HUD's collection and maintenance of records on applicants for employment, employees, and other individuals who participate in HUD programs or activities who request or receive reasonable accommodations or other appropriate modifications from HUD for medical and religious reasons.

Title V of the Rehabilitation Act of 1973, as amended, prohibits discrimination in services and employment based on disability, and Title VII of the Civil Rights Act of 1974 prohibits discrimination, including on the basis of religion. These prohibitions on discrimination require Federal agencies to provide reasonable accommodations to individuals with disabilities and those with sincerely held religious beliefs unless doing so would impose an undue hardship. In some instances, individuals may request modifications to their workspace, schedule, duties, or other requirements for documented medical reasons that may not qualify as a disability but may necessitate an appropriate modification to workplace policies and practices.

The Office of the Chief Human Capital Officer (OCHCO), processes requests for reasonable accommodations from employees and applicants for employment, respectively, who require an accommodation due to a medical or religious reason; OCHCO also processes requests based on documented medical reasons that may not qualify as a disability but that necessitate an appropriate modification to workplace policies and practices. The request, documentation provided in support of the request, any evaluation conducted internally, or by a third party under contract to HUD, the decision regarding whether to grant or deny a request, and the details and conditions of the reasonable accommodation and exception requests are all included in this system of records.

SYSTEM NAME AND NUMBER:

Human Resource (HR) Case Management Solution, HUD/OCHCO–01.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

United States Department of Housing and Urban Development Headquarters location, 451 7th Street SW, Washington, DC 20410–0001.

SYSTEM MANAGER(S):

Director, Human Capital Information System Division (HCISD), Office of the Chief Human Capital Officer (OCHCO), 451 Seventh Street SW, Washington, DC 20410–0001.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The collection and maintenance of accommodation records is authorized by the Rehabilitation Act, 29 U.S.C. 791, and Title VII of the Civil Rights Act, 42 U.S.C. 2000e, as well as Executive Orders 13164 and 14043, and 29 CFR 1605 and 1614.

PURPOSES OF THE SYSTEM:

The purpose of this system is to allow HUD to collect and maintain records on individuals (including employees and applicants for employment) requesting or receiving reasonable accommodations and religious and medical exception requests. Another purpose of this system is to monitor, process, track and report the processing of reasonable accommodation and exception requests while ensuring compliance with applicable laws and regulations, including confidentiality requirements protecting information individuals submit in support of accommodation requests and exception.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current, former HUD employees and applicants for employment who request or receive reasonable accommodations or exceptions.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, home address, email address(es), home telephone number(s), work telephone number(s), work address, protected health information, religion, vehicle license plate, legal documents and records, evidentiary records, requesters, attorneys or representatives' names, fax number, office information, employment status, history or information, employee identification number, education records, case identifier and HUD ID, medical/religious exception requests, records, forms, documentation, reasonable accommodations applications, supporting documentation, and related data fields.

RECORD SOURCE CATEGORIES:

Information is obtained from the individuals or the representatives who request and/or receive a reasonable accommodation or medical and religious exceptions from HUD, directly or indirectly from an individual's medical provider or another medical professional who evaluates the request, directly or indirectly from an individual's religious or spiritual advisors or institutions, and HUD personnel who participate in the receipt, evaluation, review, decision and implementation of reasonable accommodation and exception requests, such as hiring officials, human resource officials, supervisors and managers, reasonable accommodation officials, attorneys, and deciding officials.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside HUD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To a congressional office from the record of an individual, in response to an inquiry from the congressional office made at the request of that individual.

B. To contractors, grantees, experts, consultants, Federal agencies, and non-Federal entities, including, but not limited to, State and local governments and other research institutions or their parties, and entities and their agents with whom HUD has a contract, service agreement, grant, or cooperative agreement, when necessary to accomplish an agency function, related to a system of records, for the purposes of statistical analysis and research in support of program operations, management, performance monitoring, evaluation, risk management, and policy development, or to otherwise support the Department's mission.

C. To contractors, grantees, experts, consultants and their agents, or others performing or working under a contract, service, grant, or cooperative agreement with HUD or under contract to another agency when necessary to accomplish an agency function related to a system of records. Disclosure requirements are limited to only those data elements considered relevant to accomplishing an agency function. Individuals provided information under these routine use

conditions are subject to Privacy Act requirements and disclosure limitations imposed on the Department.

D. To appropriate agencies, entities, and persons when: (1) HUD suspects or has confirmed that there has been a breach of the system of records; (2) HUD has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, HUD, 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 HUD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

E. To another Federal agency or Federal entity, when HUD determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to 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.

F. To appropriate Federal, State, local, tribal, or governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would assist in the enforcement of civil or criminal laws and when such records, either alone or in conjunction with other information, indicate a violation or potential violation of law.

G. To a court, magistrate, administrative tribunal, or arbitrator while presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, mediation, or settlement negotiations; or in connection with criminal law proceedings; or in response to a subpoena or to a prosecution request when such records to be released are specifically approved by a court provided order. Disclosures made pursuant to this routine use are limited to when HUD determines that use of such records is relevant and necessary to the litigation, provided, however, that in each case, HUD determines that the disclosure of the records is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

H. To the Department of Justice when (a) the agency, or any component thereof; or (b) any employee of the agency in his or her official capacity; or (c) any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or (d) the United States, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation, provided, however, that in each case, the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected.''

I. To officials of labor organizations recognized under the Civil Service Reform Act when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting work conditions.

K. To the Office of Personnel Management (OPM), the Merit Systems Protection Board (and its office of the Special Counsel), the Federal Labor Relations Authority (and its General Counsel), or the Equal Employment Opportunity Commission when requested in performance of their authorized duties of exclusive representation concerning personnel policies, practices, and matters affecting work conditions.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic Records are maintained and stored in a secured network environment. Paper copies records are stored and locked in cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Paper and electronic records are retrieved by the name, case number, HUD Identification number associated with the individual.

POLICIES AND PRACTICIES FOR RETENTION AND DISPOSAL OF RECORDS:

Destroy 3 years after employee separation from the agency or all appeals are concluded whichever is later, but longer retention is authorized if required for business use.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Electronic Records are maintained and stored in an electronic encryption database system. These records can only be access based off the user's rights and privileges to the system. A multifactor identification method is required which consists of the several layers of security to access the records, such as a valid common access card, access to HUD's network, a valid User ID and password, and a Personalized Identification Number (PIN).

RECORD ACCESS PROCEDURES:

Individuals seeking to determine whether this System of Records contains information on themselves should address written inquiries to the Department of Housing and Urban Development, Office of the Chief Human Capital Officer (OCHCO), 451 7th Street SW, Washington, DC 20410–0001. For verification purposes, individuals should provide full name, current address, and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (Date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (Date). (Signature).''

CONTESTING RECORD PROCEDURES:

The HUD rule for accessing, contesting, and appealing agency determinations by the individual concerned are published in 24 CFR part 16.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Department of Housing and Urban Development, Office of the Chief Human Capital Officer (OCHCO), 451 7th Street SW, Washington, DC 20410–0001. For verification purposes, individuals should provide full name, office or organization where currently assigned, if applicable, and current address and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (Date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (Date). (Signature).''

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

N/A.

Ladonne L. White,

Departmental Privacy Officer.

[FR Doc. 2021–24892 Filed 11–15–21; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7040–N–11]

60-Day Notice of Proposed Information Collection: Public Housing Agency Executive Compensation Information; OMB Control No.: 2577–0272

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, PIH, 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:* January 18, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street SW, (L'Enfant Plaza, Room 2206), Washington, DC 20410; telephone 202–402–3400, (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at (800) 877–8339. 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 Proposal: Public Housing Agency Executive Compensation Information.

OMB Approval Number: 2577–0272.

Type of Request: Revision of currently approved collection.

Form Number: HUD–52725.

Description of the need for the information and proposed use: Pursuant to a notice issued annually (most recently PIH Notice 2019–21), HUD collects information on the compensation provided by public housing agencies (PHAs) to its employees. More specifically, under this collection PHAs are to report the compensation paid to the top management official, the top financial official, and all employees who are paid an annual salary over the compensation cap imposed by Congress in HUD's annual appropriations (Level IV of the Executive Schedule).

This reporting is similar to the information that non-profit organizations receiving federal tax exemptions are required to report to the IRS annually. Because PHAs receive significant direct federal funds HUD has been collecting compensation information to enhance regulatory oversight by HUD, as well as by state and local authorities. HUD provides the information collected to the public. The compensation data collected includes base salary, bonus, and incentive and other compensation, and the extent to which these payments are made with any Section 8 and 9 appropriated funds.

One of the primary purposes of this amendment to the PHA executive compensation information collection is to reduce the reporting burden on ALL PHAs by moving from an annual collection to collecting one year of data once every three years—this will reduce the reporting burden on PHAs by 66.7%.

While HUD may only collect PHA compensation data once every three years, PHAs are still subject to the annual compensation restrictions imposed by Congress. Therefore, all years remain subject to potential review by HUD to ensure compliance with the Annual Appropriations Act.

Respondents: Public Housing Agencies.

Estimated Number of Respondents: 4,000.

Estimated Number of Responses: 4,000.

Frequency of Response: Triennially (once every three years).

Average Hours per Response: One hour.

Total Estimated Burdens: The total burden hours is estimated to be 4,000 hours triennially. The total burden cost is estimated to be $128,080.

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. Chapter 35.

Dated: November 5, 2021.

Laura Miller-Pittman,

Chief, Office of Policy, Programs and Legislative Initiatives.

[FR Doc. 2021–24933 Filed 11–15–21; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2021–0052; FXIA16710900000–212–FF09A30000]

Marine Mammals; Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permits.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have issued the following permits to conduct certain activities with marine mammals. We issue these permits under section 104(c) of the Marine Mammal Protection Act of 1972, as amended.

ADDRESSES: Information about the applications for the permits listed in this notice is available online at *www.regulations.gov.* See **SUPPLEMENTARY INFORMATION** for details.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, by phone at 703–358–2185, via email at *DMAFR@fws.gov,* or via the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), have issued permits to conduct certain activities with marine mammals in response to permit applications that we received. Section 104(c) of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), 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, providing that certain conditions are met. A permit may be issued for public display purposes to applicants which offers a program for education or conservation purposes that meets professionally recognized standards of the public display community, for which the applicant's facilities are open to the public on a regularly scheduled basis and that access to the facilities is not limited or restricted other than by charging of an admission fee. A permit may be issued for scientific research purposes when the taking is required to further a bona fide scientific purpose and does not involve unnecessary duplication of research. This notice only informs the public that, after going through a review of the submitted application, the Service has determined that all the issuance criteria of the MMPA have been met.

Availability of Documents

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 *www.regulations.gov* and search for the appropriate permit number (*e.g.,* 12345C) provided in the following table:

Marine Mammals

Permit No.	ePermit No.	Applicant	Permit issuance date
672624	N/A	U.S. Geological Survey (USGS)	December 7, 2020.
73634A	N/A	Seward Association for the Advancement of Marine Science dba Alaska Sealife Center.	December 8, 2020.

Authorities

We issue this notice under the Marine Mammal Protection Act as amended (16 U.S.C. 1361 *et seq.*) and their implementing regulations.

Brenda Tapia,

Supervisor, Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2021–24889 Filed 11–15–21; 8:45 am]

BILLING CODE 4333–15–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting

TIME AND DATE: The Legal Services Corporation's (LSC) Board of Directors will meet Monday, November 22, 2021. The meeting will commence at 4:30 p.m., Eastern time, continuing until the conclusion of the Board's agenda.

PLACE:

Public Notice of Virtual Meeting.

LSC will conduct the November 22, 2021 meeting virtually via Zoom.

Public Observation: Unless otherwise noted herein, the Board meeting will be open to public observation. Members of the public who wish to participate remotely in the public proceedings may do so by following the directions provided below.

Directions for Open Sessions

Monday, November 22, 2021

- To join the Zoom meeting by computer, please use this link:
  - *https://lsc-gov.zoom.us/j/94947300234?pwd=a1FxNlNIbUdDaHdwWEFlOGYzSzltUT09*
  - Meeting ID: 949 4730 0234
  - Passcode: 112221
- To join the Zoom meeting with one tap from your mobile phone, please dial:
  - +13017158592,,94947300234# US (Washington DC)
  - +13126266799,,94947300234# US (Chicago)
  - Passcode: 112221
- To join the Zoom meeting by telephone, please dial any of the following numbers:
  - +1 301 715 8592 US (Washington, DC)
  - +1 312 626 6799 US (Chicago)
  - +1 646 876 9923 US (New York)
  - +1 408 638 0968 US (San Jose)
  - +1 669 900 6833 US (San Jose)
  - +1 253 215 8782 US (Tacoma)
  - +1 346 248 7799 US (Houston)
  - Meeting ID: 949 4730 0234
  - Passcode: 112221

Once connected to Zoom, please immediately mute your computer or telephone. Members of the public are asked to keep their computers or telephones muted to eliminate background noise. To avoid disrupting the meetings, please refrain from placing the call on hold if doing so will trigger recorded music or other sound.

From time to time, the Chair may solicit comments from the public. To participate in the meeting during public comment, use the 'raise your hand' or 'chat' functions in Zoom and wait to be recognized by the Chair before stating your questions and/or comments.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Meeting Schedule

1. Approval of agenda
2. Consider and act on the Board of Directors' transmittal letter to accompany the Inspector General's Semiannual Report to Congress for the period of April 1, 2021 through September 30, 2021
3. Public comment
4. Consider and act on other business
5. Consider and act on adjournment of meeting

CONTACT PERSON FOR MORE INFORMATION: Jessica Wechter, Special Assistant to the President, at (202) 295–1626. Questions may also be sent by electronic mail to *wechterj@lsc.gov.*

Non-Confidential Meeting Materials: Non-confidential meeting materials will be made available in electronic format at least 24 hours in advance of the meeting on the LSC website, at *https://www.lsc.gov/about-lsc/board-meeting-materials.*

Dated: November 11, 2021.

Jessica L. Wechter,

Special Assistant to the President, Legal Services Corporation.

[FR Doc. 2021–25037 Filed 11–12–21; 11:15 am]

BILLING CODE 7050–01–P

OFFICE OF MANAGEMENT AND BUDGET

Determination of the Acting OMB Director Regarding the Revised Safer Federal Workforce Task Force Guidance for Federal Contractors and the Revised Economy & Efficiency Analysis

AGENCY: Executive Office of the President, Office of Management and Budget.

ACTION: Notice of determination; request for comments.

SUMMARY: The Director of the Office of Management and Budget (''OMB'') determines that compliance by Federal contractors and subcontractors with the COVID–19 workplace safety protocols detailed in the Safer Federal Workforce Task Force (''Safer Federal Workforce Task Force'' or the ''Task Force'') guidance (the ''Guidance'') to be issued on November 10, 2021, will promote economy and efficiency in Federal contracting by reducing absenteeism and decreasing labor costs for contractors and subcontractors working on or in connection with a Federal Government contract, and the Director approves the guidance. This notice accordingly rescinds and supersedes the Director's prior notice issued on September 24, 2021.

DATES: To be ensured consideration, comments must be received on or before December 16, 2021.

ADDRESSES: You should submit comments via the Federal eRulemaking Portal at *https://www.regulations.gov/.* Follow the instructions for submitting comments.

Please be advised OMB will post all comments received that relate to this notice of determination on *https://www.regulations.gov* without making any change to the comments or redacting any information.

All comments posted are available and accessible to the public. So, do not include any information you would not like to be made publicly available, such as Social Security numbers, personal addresses, telephone numbers, and email addresses. It is the responsibility of the commenter to safeguard personal information.

FOR FURTHER INFORMATION CONTACT: Cristin Dorgelo, 725 17th Street NW, Email address: *cristin.a.dorgelo@omb.eop.gov,* telephone number: (202) 456–4066. Because of delays in the receipt of regular mail related to security screening, respondents are encouraged to use electronic communications.

SUPPLEMENTARY INFORMATION: Section 2 of Executive Order 14042 (''Executive Order 14042'' or the ''order'') requires that, before Federal contractors and subcontractors must adhere to any guidance from the Task Force, the Director of OMB must approve such guidance and determine that such guidance will promote economy and efficiency in Federal contracting if adhered to by Government contractors and subcontractors. Based on my review of the Task Force's COVID–19 Workplace Safety: Guidance for Federal Contractors and Subcontractors, scheduled for issuance on November 10, 2021 (reproduced in relevant part in Part I below), as well as the economy-and-efficiency analysis presented in Part II below, and exercising the President's authority under the Federal Property and Administrative Services Act (see 3 U.S.C. 301) delegated to me through Executive Order 14042, I approve the Guidance and have determined that the COVID–19-workplace safety protocols detailed in that Guidance will promote economy and efficiency in Federal contracting if adhered to by Government contractors and subcontractors. This notice accordingly rescinds and supersedes my prior notice issued on September 24, 2021. 86 FR 53691.

This notice consists of the following sections. Part I consists of revised Guidance from the Task Force. Part II consists of an economic analysis of the COVID–19-workplace safety protocols detailed in such Guidance and the effect on economy and efficiency in Federal procurement. Part III addresses procedural requirements.

Part I. Safer Federal Workforce Task Force Guidance

On September 9, President Biden announced his Path Out of the Pandemic: COVID–19 Action Plan. One of the main goals of this science-based plan is to get more people vaccinated. As part of that plan, the President signed Executive Order 14042, Ensuring Adequate COVID Safety Protocols for Federal Contractors, which directs executive departments and agencies, including independent establishments subject to the Federal Property and Administrative Services Act, 40 U.S.C. 102(4)(A), to ensure that covered contracts and contract-like instruments include a clause (''the clause'') that the contractor and any subcontractors (at any tier) shall incorporate into lower-tier subcontracts. This clause shall specify that the contractor or subcontractor shall, for the duration of the contract, comply with all guidance for contractor or subcontractor workplace locations published by the Task Force, provided that the Director of OMB approves the Task Force Guidance and determines that the Guidance, if adhered to by covered contractors, will promote economy and efficiency in Federal contracting.

The actions directed by the order will ensure that parties who contract with the Federal Government provide COVID–19 safeguards in workplaces with individuals working on or in connection with a Federal Government contract or contract-like instrument. These workplace safety protocols will apply to all covered contractor employees, including contractor or subcontractor employees in covered contractor workplaces who are not working on a Federal Government contract or contract-like instrument. These safeguards will decrease the spread of SARS–CoV–2, the virus that causes COVID–19, which will decrease worker absence, reduce labor costs, and improve the efficiency of contractors and subcontractors performing work for the Federal Government.

Pursuant to this Guidance, and in addition to any requirements or workplace safety protocols that are applicable because a contractor or subcontractor employee is present at a Federal workplace, Federal contractors and subcontractors with a covered contract will be required to conform to the following workplace safety protocols:

1. COVID–19 vaccination of covered contractor employees, except in limited circumstances where an employee is legally entitled to an accommodation;

2. Compliance by individuals, including covered contractor employees and visitors, with the Guidance related to masking and physical distancing while in covered contractor workplaces; and

3. Designation by covered contractors of a person or persons to coordinate COVID–19 workplace safety efforts at covered contractor workplaces.

The order also sets out a process for OMB and the Safer Federal Workforce Task Force to update the Guidance for covered contractors, which the Task Force will consider doing based on future changes to Centers for Disease Control and Prevention (''CDC'') COVID–19 guidance and as warranted by the circumstances of the pandemic and public health conditions. It also sets out a process for the Federal Acquisition

Regulatory Council (''FAR Council'') to implement such protocols and guidance for covered Federal procurement solicitations and contracts subject to the Federal Acquisition Regulation (''FAR'') and for agencies that are responsible for covered contracts and contract-like instruments not subject to the FAR to take prompt action to ensure that those covered contracts and contract-like instruments include the clause, consistent with the order.

Covered contractors shall adhere to the requirements of this Guidance.

A. Definitions

Community transmission—means the level of community transmission as set forth in the CDC COVID–19 Data Tracker County View.[1]

Contract and contract-like instrument—has the meaning set forth in the Department of Labor's proposed rule, ''Increasing the Minimum Wage for Federal Contractors,'' 86 FR 38816, 38887 (July 22, 2021). If the Department of Labor issues a final rule relating to that proposed rule, this term shall have the meaning set forth in that final rule.

That proposed rule defines a contract or contract-like instrument as an agreement between two or more parties creating obligations that are enforceable or otherwise recognizable at law. This definition includes, but is not limited to, a mutually binding legal relationship obligating one party to furnish services (including construction) and another party to pay for them. The term contract includes all contracts and any subcontracts of any tier thereunder, whether negotiated or advertised, including any procurement actions, lease agreements, cooperative agreements, provider agreements, intergovernmental service agreements, service agreements, licenses, permits, or any other type of agreement, regardless of nomenclature, type, or particular form, and whether entered into verbally or in writing. The term contract shall be interpreted broadly as to include, but not be limited to, any contract within the definition provided in the FAR at 48 CFR chapter 1 or applicable Federal statutes. This definition includes, but is not limited to, any contract that may be covered under any Federal procurement statute. Contracts may be the result of competitive bidding or awarded to a single source under applicable authority to do so. In addition to bilateral instruments, contracts include, but are not limited to, awards and notices of awards; job orders or task letters issued under basic ordering agreements; letter contracts; orders, such as purchase orders, under which the contract becomes effective by written acceptance or performance; exercised contract options; and bilateral contract modifications. The term contract includes contracts covered by the Service Contract Act, contracts covered by the Davis-Bacon Act, concessions contracts not otherwise subject to the Service Contract Act, and contracts in connection with Federal property or land and related to offering services for Federal employees, their dependents, or the general public.

Contractor or subcontractor workplace location—means a location where covered contract employees work, including a covered contractor workplace or Federal workplace.

Covered contract—means any contract or contract-like instrument that includes the clause described in Section 2(a) of the order.

Covered contractor—means a prime contractor or subcontractor at any tier who is party to a covered contract.

Covered contractor employee—means any full-time or part-time employee of a covered contractor working on or in connection with a covered contract or working at a covered contractor workplace. This includes employees of covered contractors who are not themselves working on or in connection with a covered contract.

Covered contractor workplace—means a location controlled by a covered contractor at which any employee of a covered contractor working on or in connection with a covered contract is likely to be present during the period of performance for a covered contract. A covered contractor workplace does not include a covered contractor employee's residence.

Federal workplace—means any place, site, installation, building, room, or facility in which any Federal executive department or agency conducts official business, or is within an executive department or agency's jurisdiction, custody, or control.

Fully vaccinated—people are considered fully vaccinated for COVID–19 two weeks after they have received the second dose in a two-dose series, or two weeks after they have received a single-dose vaccine.[2] There is currently no post-vaccination time limit on fully vaccinated status; should such a limit be determined by the Centers for Disease Control and Prevention, that limit will be considered by the Task Force and OMB for possible updating of this Guidance.

For purposes of this Guidance, people are considered fully vaccinated if they have received COVID–19 vaccines currently approved or authorized for emergency use by the U.S. Food and Drug Administration (Pfizer-BioNTech, Moderna, and Johnson & Johnson [J&J]/Janssen COVID–19 vaccines) or COVID–19 vaccines that have been listed for emergency use by the World Health Organization (*e.g.,* AstraZeneca/Oxford). More information is available at Interim Clinical Considerations for Use of COVID–19 Vaccines | CDC.[3]

Clinical trial participants from a U.S. site who are documented to have received the full series of an ''active'' (not placebo) COVID–19 vaccine candidate, for which vaccine efficacy has been independently confirmed (*e.g.,* by a data and safety monitoring board), can be considered fully vaccinated two weeks after they have completed the vaccine series. Currently, the Novavax COVID–19 vaccine meets these criteria. More information is available at the CDC website.[4]

Mask—means any mask that is consistent with CDC recommendations.[5] This may include the following: Disposable masks, masks that fit properly (snugly around the nose and chin with no large gaps around the sides of the face), masks made with breathable fabric (such as cotton), masks made with tightly woven fabric (*i.e.,* fabrics that do not let light pass through when held up to a light source), masks with two or three layers, masks with inner filter pockets, and filtering facepiece respirators that are approved by the National Institute for Occupational Safety and Health or consistent with international standards. The following do not constitute masks for purposes of this Guidance: Masks with exhalation valves, vents, or other openings; face shields only (without mask); or masks with single-layer fabric or thin fabric that does not block light.

B. Requirements

Covered contractors are responsible for ensuring that covered contractor employees comply with the workplace

[1] CDC, COVID–19 Integrated County View, *https://covid.cdc.gov/covid-data-tracker/#county-view.*

[2] CDC, When You've Been Fully Vaccinated (last updated Oct. 15, 2021), *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html.*

[3] CDC, Interim Clinical Considerations for Use of COVID–19 Vaccines, *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.*

[4] CDC, People who received COVID–19 vaccine as part of a clinical trial in the United States, *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#vaccinated-part-clinical-trail.*

[5] CDC, Types of Masks and Respirators (Sept. 23, 2021), *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html.*

safety protocols detailed below. Covered contractor employees must also comply with agency COVID–19 workplace safety requirements while in Federal workplaces.

Consistent with applicable law, agencies are strongly encouraged to incorporate a clause requiring compliance with this Guidance into contracts that are not covered or directly addressed by the order because the contract is under the Simplified Acquisition Threshold as defined in section 2.101 of the FAR or is a contract or subcontract for the manufacturing of products.

Agencies are also strongly encouraged to incorporate a clause requiring compliance with this Guidance into existing contracts and contract-like instruments prior to the date upon which the order requires inclusion of the clause.

1. Vaccination of Covered Contractor Employees, Except in Limited Circumstances Where an Employee Is Legally Entitled to an Accommodation

Covered contractors must ensure that all covered contractor employees are fully vaccinated for COVID–19, unless the employee is legally entitled to an accommodation. Covered contractor employees must be fully vaccinated no later than January 18, 2022. After that date, all covered contractor employees must be fully vaccinated by the first day of the period of performance on a newly awarded covered contract, and by the first day of the period of performance on an exercised option or extended or renewed contract when the clause has been incorporated into the covered contract.

A covered contractor may be required to provide an accommodation to covered contractor employees who communicate to the covered contractor that they are not vaccinated against COVID–19 because of a disability (which would include medical conditions) or because of a sincerely held religious belief, practice, or observance. A covered contractor should review and consider what, if any, accommodation it must offer. Requests for ''medical accommodation'' or ''medical exceptions'' should be treated as requests for a disability accommodation.

Should a Federal agency have an urgent, mission-critical need for a covered contractor to have covered contractor employees begin work on a covered contract or at a covered workplace before becoming fully vaccinated, the agency head may approve an exception for the covered contractor—in the case of such limited exceptions, the covered contractor must ensure these covered contractor employees are fully vaccinated within 60 days of beginning work on a covered contract or at a covered workplace. The covered contractor must further ensure that such employees comply with masking and physical distancing requirements for not fully vaccinated individuals in covered workplaces prior to being fully vaccinated.

The covered contractor must review its covered employees' documentation to prove vaccination status. Covered contractors must require covered contractor employees to show or provide their employer with one of the following documents: A copy of the record of immunization from a health care provider or pharmacy, a copy of the COVID–19 Vaccination Record Card (CDC Form MLS–319813_r, published on September 3, 2020), a copy of medical records documenting the vaccination, a copy of immunization records from a public health or State immunization information system, or a copy of any other official documentation verifying vaccination with information on the vaccine name, date(s) of administration, and the name of health care professional or clinic site administering vaccine. Covered contractors may allow covered contractor employees to show or provide to their employer a digital copy of such records, including, for example, a digital photograph, scanned image, or PDF of such a record.

The covered contractor shall ensure compliance with the requirements in this Guidance related to the showing or provision of proper vaccination documentation.

Covered contractors are strongly encouraged to incorporate similar vaccination requirements into their non-covered contracts and agreements with non-covered contractors whose employees perform work at covered contractor workplaces but who do not work on or in connection with a Federal contract, such as those contracts and agreements related to the provision of food services, onsite security, or groundskeeping services at covered contractor workplaces.

2. Requirements Related To Masking and Physical Distancing While in Covered Contractor Workplaces

Covered contractors must ensure that all individuals, including covered contractor employees and visitors, comply with published CDC guidance for masking and physical distancing at a covered contractor workplace, as discussed further in this Guidance.

In addition to the guidance set forth below, CDC's guidance for mask wearing and physical distancing in specific settings, including healthcare, transportation, correctional and detention facilities, and schools, must be followed, as applicable.

In areas of high or substantial community transmission, fully vaccinated people must wear a mask in indoor settings, except for limited exceptions discussed in this Guidance. In areas of low or moderate community transmission, fully vaccinated people do not need to wear a mask. Fully vaccinated individuals do not need to physically distance regardless of the level of transmission in the area.

Individuals who are not fully vaccinated must wear a mask indoors and in certain outdoor settings (see below) regardless of the level of community transmission in the area. To the extent practicable, individuals who are not fully vaccinated should maintain a distance of at least six feet from others at all times, including in offices, conference rooms, and all other communal and work spaces.

Covered contractors must require individuals in covered contractor workplaces who are required to wear a mask to:

- Wear appropriate masks consistently and correctly (over mouth and nose).
- Wear appropriate masks in any common areas or shared workspaces (including open floorplan office space, cubicle embankments, and conference rooms).
- For individuals who are not fully vaccinated, wear a mask in crowded outdoor settings or during outdoor activities that involve sustained close contact with other people who are not fully vaccinated, consistent with CDC guidance.

A covered contractor may be required to provide an accommodation to covered contractor employees who communicate to the covered contractor that they cannot wear a mask because of a disability (which would include medical conditions) or because of a sincerely held religious belief, practice, or observance. A covered contractor should review and consider what, if any, accommodation it must offer.

Covered contractors may provide for exceptions to mask wearing and/or physical distancing requirements consistent with CDC guidelines, for example, when an individual is alone in an office with floor to ceiling walls and a closed door, or for a limited time when eating or drinking and maintaining appropriate distancing. Covered contractors may also provide

exceptions for covered contractor employees engaging in activities in which a mask may get wet; high intensity activities where covered contractor employees are unable to wear a mask because of difficulty breathing; or activities for which wearing a mask would create a risk to workplace health, safety, or job duty as determined by a workplace risk assessment.[6] Any such exceptions must be approved in writing by a duly authorized representative of the covered contractor to ensure compliance with this Guidance at covered contractor workplaces, as discussed further below.

Masked individuals may be asked to lower their masks briefly for identification purposes in compliance with safety and security requirements.

Covered contractors must check the CDC COVID–19 Data Tracker County View website for community transmission information in all areas where they have a covered contractor workplace at least weekly to determine proper workplace safety protocols.[7] When the level of community transmission in the area of a covered contractor workplace increases from low or moderate to substantial or high, contractors and subcontractors should put in place more protective workplace safety protocols consistent with published guidelines. However, when the level of community transmission in the area of a covered contractor workplace is reduced from high or substantial to moderate or low, the level of community transmission must remain at that lower level for at least two consecutive weeks before the covered contractor utilizes those protocols recommended for areas of moderate or low community transmission.

3. Designation by Covered Contractors of a Person or Persons To Coordinate COVID–19 Workplace Safety Efforts at Covered Contractor Workplaces

Covered contractors shall designate a person or persons to coordinate implementation of and compliance with this Guidance and the workplace safety protocols detailed herein at covered contractor workplaces. The designated person or persons may be the same individual(s) responsible for implementing any additional COVID–19 workplace safety protocols required by local, State, or Federal law, and their responsibilities to coordinate COVID–19 workplace safety protocols may comprise some or all of their regular duties.

The designated individual (or individuals) must ensure that information on required COVID–19 workplace safety protocols is provided to covered contractor employees and all other individuals likely to be present at covered contractor workplaces, including by communicating the required workplace safety protocols and related policies by email, websites, memoranda, flyers, or other means and posting signage at covered contractor workplaces that sets forth the requirements and workplace safety protocols in this Guidance in a readily understandable manner. This includes communicating the COVID–19 workplace safety protocols and requirements related to masking and physical distancing to visitors and all other individuals present at covered contractor workplaces. The designated individual (or individuals) must also ensure that covered contractor employees comply with the requirements in this Guidance related to the showing or provision of proper vaccination documentation.

Frequently Asked Questions

Frequently Asked Questions regarding this Guidance can be found here: *https://www.saferfederalworkforce.gov/faq/contractors/.*

All Task Force Guidance, FAQs, and additional information for Federal contractors and subcontractors can be found here: *https://www.saferfederalworkforce.gov/contractors/.*

Part II. Economy-and-Efficiency Analysis

The following analysis outlines the ways in which the Guidance set forth in Part I will promote economy and efficiency in Federal procurement.

The Guidance requires vaccination of covered contractor employees, except in limited circumstances where an employee is legally entitled to an accommodation. It imposes requirements related to masking and physical distancing in covered contractor workplaces. And it requires covered contractors to designate a person or persons to coordinate COVID–19 workplace safety efforts at covered contractor workplaces.

The Guidance is issued pursuant to Executive Order 14042, which the President promulgated, in part, under the Federal Property and Administrative Services Act (FPASA). The FPASA, 40 U.S.C. 101 *et seq.* provides that the President ''may prescribe policies and directives that the President considers necessary to carry out'' the Act, which includes a purpose of ''provid[ing] the Federal Government with an economical and efficient system for . . . [p]rocuring and supplying property and nonpersonal services.'' 40 U.S.C. 101(1), 121(a).

This analysis of the economic impact of the Guidance is based on OMB's subject matter expertise and OMB's review and analysis of the academic literature on interventions to prevent the spread of COVID–19.

As explained below, the overall effect of enacting these protocols for Federal contractors and subcontractors will be to decrease the spread of COVID–19, which will in turn decrease worker absence, save labor costs on net, and thereby improve efficiency in Federal contracting. Indeed, numerous private companies have undertaken vaccine mandates that were announced or take effect before the Federal Government's mandate on Federal contractors takes effect and private companies have also imposed masking and physical distancing requirements at their workplaces. Just as these private businesses have concluded that vaccination, masking, and physical distancing requirements will make their operations more efficient and competitive in the market, we have concluded that the Guidance will realize economy and efficiency in Federal contracting.

A. COVID–19 Infection Imposes Significant Costs on Contractors and the Federal Government

The primary goal of the safety protocols is to reduce the spread of COVID–19 among contractor employees. COVID–19 is a highly communicable disease that tends to spread between people who are indoors, sharing space, and in close quarters—conditions common in typical workplaces.[8] There is also evidence that COVID–19 can be spread by asymptomatic individuals. One study estimated that more than half of transmissions come from individuals who do not have symptoms (Johansson et al., 2021). Individuals who do not have symptoms are likely to continue to report to work and therefore may spread the disease to their coworkers. As such, safety protocols applied even in the absence of observable illness among employees can meaningfully reduce the spread of COVID–19. Moreover, because employees working at a single workplace will regularly come into contact, safety protocols applied to all

[6] OSHA, Recommended Practices for Safety and Health Programs, *https://www.osha.gov/safety-management.*

[7] CDC, COVID–19 Integrated County View, *https://covid.cdc.gov/covid-data-tracker/#county-view.*

[8] See U.S. Environmental Protection Agency, Indoor Air and Coronavirus (COVID–19), *https://www.epa.gov/coronavirus/indoor-air-and-coronavirus-covid-19.*

employees in a workplace can meaningfully reduce the spread of COVID–19.

The CDC recommends that individuals remain isolated for ten days after symptom onset, which would mean workers who catch the virus can miss up to eight days of work.[9] Furthermore, those individuals could infect other workers, who would also miss eight days of work. Additional exposed workers would likely need to quarantine and would also miss work.

Workers unable to work generate substantial costs on employers. An imperfect proxy for the cost to an employer of a foregone hour of work is the worker's hourly pay. We calculate the average hourly wage for a Federal contractor to be approximately $31.51, making the average pay for eight days $2,016.[10] Wages are higher in Washington, DC, Maryland and Virginia, where many contractors are located, ranging from $33.36 in Virginia to $42.83 in Washington, DC, making the average pay for eight days in those areas $2,135 and $2,741, respectively. Such costs are substantial and, if borne by contractors, such costs would be expected to be passed on to the Federal Government, either in direct cost or lower quality, including delays.

Fortunately, vaccines, masks, and physical distancing have all been proven to reduce the prevalence of COVID–19 infection, and vaccines have been shown to greatly reduce the severity of breakthrough infections. And vaccines, masking, and physical distancing are all low-cost interventions.

B. COVID–19 Vaccination Reduces Net Costs

Requiring any workers who have not yet done so to receive a COVID–19 vaccine would generate meaningful efficiency gains for Federal contractors. COVID–19 vaccines provide strong and persistent protection against infection, illness, and hospitalization (see Tenforde, et al., 2021 and references). Reducing the number of infected people mechanically reduces transmission, and some preliminary evidence also indicates that vaccines also reduce transmission by people who contract ''breakthrough'' infections (Ke, et al., 2021). The vaccine requirement in the Guidance buttresses other workplace-specific safety protocols and provides protection against infection outside of the workplace, increasing the likelihood that the full set of protocols will prevent infection and illness and preserve the productivity of people working on or in connection with Federal contracts.[11]

Because vaccines are widely available for free, the cost of implementing a vaccine mandate is largely limited to administrative costs associated with distributing information about the mandate and tracking employees' vaccination status. Such costs are likely to be small.[12] Other costs of vaccination include employees quitting and using sick time when experiencing side effects from vaccination. However, based on experiences shared by private companies detailed below, we expect few employees to quit because of the vaccine mandate, and side effects lead to significantly less sick leave than COVID–19 infection. And unlike COVID–19 infection, side effects are not contagious to other employees.

Consistent with the view that COVID–19 vaccines promote economy and efficiency, numerous private companies have undertaken vaccine mandates that were announced or take effect before the Federal Government's mandate on Federal contractors takes effect. Led originally by companies like United Airlines and Tyson Foods, a wide and growing swath of private companies have determined that vaccine mandates are net beneficial to their companies.[13]

While anecdotal reports suggest that vaccine mandates may lead some workers to quit their jobs rather than comply, which could create some cost associated with replacing them, we know of no systematic evidence that this has been a widespread phenomenon, or that it would be likely to occur among employees of Federal contractors. In fact, the experience of private companies is to the contrary. For example, United Airlines reported in October 2021 that 99.7 percent of the airline's workforce complied with the vaccination requirements, Tyson Foods reported more than 96 percent of its workforce is now vaccinated, and healthcare providers such as California's Kaiser Permanente reported placing only two percent of employees on administrative leave for failing to comply with vaccine requirements.[14] And finally, even if some non-negligible number of workers were to quit rather than comply with a vaccine mandate, the cost of replacing those workers would be a one-time cost, while the benefits of increased vaccination (including among replacement workers, who would be vaccinated) would be long-lasting.

C. Masking and Physical Distancing Reduces Net Costs

COVID–19 is generally thought to be spread by respiratory particles and aerosols.[15] Masking and physical distancing have proven effective in reducing the spread of COVID–19. One study found that communities with the greatest physical distancing had a 31 percent lower risk of COVID–19 than communities with poor physical distancing, and that communities where individuals reported always using face masks outside of the home, even with poor physical distancing, had 62 percent reduced risk of COVID–19 compared to communities where face masks were never worn (Kwon et al., 2020). Another study found that full population masking reduces transmission of the virus by 25.8 percent (Leech et al., 2021). Similarly, a study of masking and ventilation improvements in Georgia schools found that COVID–19 incidence was 37 percent lower in schools where masks were required and 39 percent lower in schools with improved ventilation

[9] See Centers for Disease Control and Prevention, Recommendations for Ending Isolation (last updated Sept. 14, 2021), *https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html#anchor_1631308518116.*

[10] This calculation uses the distribution of NAICS codes in the contractor population and average salary of those NAICS codes from the Occupational Employment and Wage Statistics program at the Bureau of Labor Statistics, *https://www.bls.gov/oes/.*

[11] Note that the other safety protocols discussed above will still be appropriate even after the vaccine requirement is implemented, *e.g.,* to protect against breakthrough infections and emerging variants of the virus, or for the benefit of workers who may be unable to receive a vaccine for medical or religious reasons, until such time as public health conditions improve and CDC guidance related to masking and physical distancing changes.

[12] For example, the Occupational Safety and Health Administration estimated that providing information would take ten minutes per firm (84 FR 61476 cl. 3) and that tracking employees' vaccination status would take five minutes per employee (id. 84 FR 61488 cl. 2).

[13] The Major Companies Requiring Workers to Get COVID Vaccines, Fortune (Aug. 23, 2021), *https://fortune.com/2021/08/23/companies-requiring-vaccines-workers-vaccination-mandatory/.* See greater discussion on page 12 of the White House Vaccination Requirements Report (Oct. 2021), *https://www.whitehouse.gov/wp-content/uploads/2021/10/Vaccination-Requirements-Report.pdf.*

[14] COVID Vaccine Some 5 Percent of Unvaccinated Adults Have Quit Their Jobs Over a Mandate Survey Shows CNBC (Oct. 28, 2021), *https://www.cnbc.com/2021/10/28/covid-vaccine-some-5percent-of-unvaccinated-adults-have-quit-their-jobs-over-a-mandate-survey-shows.html;* How Tyson Foods Got 60,500 Workers to Get the Coronavirus Vaccine Quickly, N.Y. Times (Nov. 4, 2021), *https://www.nytimes.com/2021/11/04/business/tyson-vaccine-mandate.html.* Vaccine mandates stoked fears of labor shortages. But hospitals say they're working, Washington Post (Oct. 16, 2021), *https://www.washingtonpost.com/health/2021/10/16/hospital-covid-vaccine-mandate/.*

[15] CDC, Prevent Getting Sick: How COVID Spreads (last updated July 14, 2021), *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

(Gettings et al., 2021). This research shows that masking, physical distancing, and improved ventilation will all reduce the likelihood that COVID–19 spreads among the contractor workforce. These preventative measures will decrease worker absence and allow contract workers to continue their work without the need to take time off to recover from COVID–19. Thus, mask wearing and physical distancing are likely to reduce the spread of COVID–19 within contractor workplaces, reducing worker absence and maintaining productivity.

The costs of masking and physical distancing are minimal. For example, contractors may have to pay for masks for their employees. Masks can cost as little as $0.13 per mask and would need to be provided only to employees who do not already have their own masks.[16] Physical distancing can often be done without additional costs. Numerous private companies like Walmart require all employees to wear masks and physically distance, embodying a judgment that these mitigation measures promote economy and efficiency in the workplace.[17]

D. Conclusion

For these reasons, it is OMB's expert opinion that the Guidance will promote economy and efficiency in Federal Government procurement. All plans for economic recovery and growth are predicated on the need to prevent additional spread of the COVID–19 virus and facilitate vaccinations, and no employer, whether public or private, can expect to see increased productivity or economic efficiency without a healthy workforce. The safety protocols that are set forth by the Safer Federal Workforce Task Force are meant to ensure that COVID–19 does not easily spread within the workplace, so that Federal contractor employees can continue to be productive.

E. References

Gettings, Jenna, Michaila Czarnik, Elana Morris et al. 2021. ''Mask Use and Ventilation Improvements to Reduce COVID–19 Incidence in Elementary Schools—Georgia, November 16–December 11, 2020.'' *Morbidity and Mortality Weekly Report* 70(21): 779–784.

Johansson, Michael A., Talia M. Quandelacy, Sarah Kada et al. 2021. ''SARS–CoV–2 Transmission from People Without COVID–19 Symptoms.'' JAMA Network Open 4(1): e2035057.

Ke, Ruian, Pamela Martinez, Rebecca Lee Smith, et al. 2021. ''Longitudinal analysis of SARS–CoV–2 vaccine breakthrough infections reveal limited infectious virus shedding and restricted tissue distribution.'' Preprint, *https://www.medrxiv.org/content/10.1101/2021.08.30.21262701v1.*

Kwon, Sohee, Amit D. Joshi, Chun-Han Lo et al. 2021. ''Association of social distancing and face mask use with risk of COVID–19.'' Nature Communications 12.

Leech, Gavin, Charlie Rogers-Smith, Jonas B. Sandbrink et al. 2021. ''Mass mask-wearing notably reduces COVID–19 transmission.'' medRxiv.

Tenforde, Mark W., Wesley H. Self, Eric A. Naioti, et al. 2021. ''Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID–19 Associated Hospitalizations Among Adults—United States, March–July 2021.'' *Morbidity and Mortality Weekly Report* 70(34): 1156–1162.

Part III. Procedural Requirements

A. Public Contract Requirements Under Public Law 111–350

I am making my determination pursuant to a Presidential delegation under 3 U.S.C. 301. That determination is therefore not subject to the procedural requirements of Public Law 111–350, codified at 41 U.S.C. 1707. *See NRDC, Inc.* v. *U.S. Dep't of State,* 658 F. Supp. 2d 105, 109 & n.5, 111 (D.D.C. 2009) (when an agency acts pursuant to 3 U.S.C. 301, the agency ''stands in the President's shoes'' and that action is ''not reviewable under the APA''); *Detroit Int'l Bridge Co.* v. *Canada,* 189 F. Supp. 3d 85, 100 (D.D.C. 2016) (''Several cases have concluded that an agency's action on behalf of the President, involving discretionary authority committed to the President, is 'presidential' and unreviewable under the APA.''). To the extent that 41 U.S.C. 1707 is applicable to my determination set forth in this document, there are urgent and compelling circumstances that justify departing from the notice-and-comment and delayed-effective-date requirements in 41 U.S.C. 1707.

The notice-and-comment and delayed-effective-date requirements of subsections (a) and (b) of 41 U.S.C. 1707 ''may be waived by the officer authorized to issue a procurement policy, regulation, procedure, or form if urgent and compelling circumstances make compliance with the requirements impracticable.'' 41 U.S.C. 1707(d). This statutory exception is implemented in FAR section 1.501–3, which provides that ''[a]dvance comments need not be solicited when urgent and compelling circumstances make solicitation impracticable prior to the effective date of the coverage, such as when a new statute must be implemented in a relative short period of time.''

Urgent and compelling circumstances justify waiving the notice-and-comment requirement for this notice. This is a once in a generation pandemic, which has already resulted in more than 46,405,253 cases of COVID–19, hospitalized more than 3,283,045 Americans, and taken more than 752,196 American lives. The pandemic continues to present an imminent threat to the health and safety of the American people, including due to the emergence of the B.1.617.2 (Delta) variant, which is a variant of concern that spreads more easily than previously discovered variants of SARS–CoV–2. This threat reaches all Americans, including those working for Federal contractors and subcontractors. The Guidance directly addresses this imminent threat by requiring vaccination. The CDC has determined that the best way to slow the spread of COVID–19, including preventing infection by the Delta variant, is for individuals to get vaccinated. According to the CDC, vaccinated individuals are 5 times less likely to be infected and 10 times less likely to experience hospitalization or death due to COVID–19 than unvaccinated individuals. The Guidance thus promotes the most important, urgent public health measure to slow the spread of COVID–19 among Federal contractors and subcontractors—which is critical to avoiding worker absence and unnecessary labor costs that could hinder the efficiency of federal contracting.

The minimum delay required by subsections (a) and (b) of 41 U.S.C. 1707 is also incompatible with a fundamental purpose of issuing this determination. The Guidance set forth in Part I changes the vaccination deadline for Federal contractors from December 8, 2021, to January 18, 2022. If the determination implementing this change were required to comply with subsections (a) and (b) of 41 U.S.C. 1707 (requiring 30 days for comment, and another 30 days to become effective), the earliest possible effective date for this determination would be January 9, 2022. But waiting until January for this determination to become effective would prevent the change in deadlines from having practical effect, as Federal contractors and subcontractors would still be legally obligated to meet the December 8, 2021, vaccination deadline until this determination became effective. That alone establishes urgent and compelling

[16] Mask costs were taken from a search of Amazon and would likely be lower for a contractor who would be able to order in bulk.

[17] The Major Companies Requiring Workers to Get COVID Vaccines, Fortune (Aug. 23, 2021), *https://fortune.com/2021/08/23/companies-requiring-vaccines-workers-vaccination-mandatory/.*

circumstances to warrant making this determination immediately effective.

Additionally, even if there were no prior deadline that contractors and subcontractors were obligated to meet, urgent and compelling circumstances would still exist because the broader economy-and-efficiency purpose of this determination would be severely undermined by the minimum delay required under subsections (a) and (b) of 41 U.S.C. 1707. As an initial matter, such a delay would interfere with an important purpose of the Task Force Guidance—aligning the vaccination deadline for Federal contractors with the vaccination deadline for private companies under recent regulatory actions. In particular, the Occupational Safety and Health Administration (OSHA) issued an Emergency Temporary Standard (ETS) requiring employers with 100 or more employees to ensure their workers are fully vaccinated or tested for COVID–19 on at least a weekly basis, and the Centers for Medicare & Medicaid Services (CMS) issued a rule requiring health care workers at facilities participating in Medicare and Medicaid to be fully vaccinated. 86 FR 61402; 86 FR 61555. Those rules set a deadline of January 4, 2022, for employees to receive their final COVID–19 vaccination dose—*i.e.,* January 18, 2022, for a fully vaccinated covered workforce. The Task Force's decision to set the same deadline for Federal contractors and subcontractors will make it easier for private employers to administer successful vaccination policies across their workforce and will allow Federal contractors and subcontractors to implement their requirements on the same timeline as other employers in their industries.[18] For example, a large employer covered by the ETS may have some but not all of their workplaces covered by the vaccination requirement for Federal contractors and subcontractors. For such an employer, that would mean some workplaces are governed by the ETS and some by the Task Force Guidance. Or, an employer may have some workers covered by the CMS rule, and other workers covered by the vaccination requirement for Federal contractors and subcontractors. For employers in these circumstances, having the same deadline across all requirements will promote consistency and administrability of public health standards, and eliminate potential confusion and frustration that disparate deadlines could produce. It could also avoid needless costs in having multiple systems of records and internal accountability established for different deadlines. Ensuring that private employers do not need to meet different compliance dates across different Federal vaccination policies is thus important to the success of their vaccination programs and to promoting economy and efficiency in Federal procurement.

Moreover, in order for such alignment to be effective, employers require regulatory certainty in the near-term. An immediately effective notice gives contractors and subcontractors a clear understanding not only of their responsibilities under Federal law but also the deadline for complying with those responsibilities. By contrast, absent an immediately effective determination of that deadline, such employers would have to wait until comments are received and a determination is finalized to know with certainty the deadline for ensuring that their covered employees are fully vaccinated. That would cause much of the administrability problems and frustration that alignment is intended to avoid, undermining the critical efforts to curb the spread of COVID–19 among Federal contractors and subcontractors and preventing alignment of the relevant deadlines.

Compliance with the procedural requirements of 41 U.S.C. 1707(a) and 1707(b) would fundamentally undermine the effort to provide private companies with aligned deadlines and regulatory certainty, as outlined above. As noted above, under those requirements the earliest effective date for this determination would be January 9, 2022. Simply put, that is far too late to provide regulatory certainty for Federal contractors, as that is *past* the date that covered employees of covered Federal contractors must receive their final COVID–19 vaccination dose (January 4, 2022), and it is less than ten days before the deadline for covered contractor employees to be fully vaccinated (January 18, 2022). Thus, compliance with the procedural requirements of 41 U.S.C. 1707(a) and 1707(b) would undermine the success of the Federal Government's vaccination efforts and economy and efficiency in Federal procurement.

Thus, to the extent that it is found that my determination is subject to the procedural requirements in 41 U.S.C. 1707, I have concluded that urgent and compelling circumstances exist under section 1707(d). The requirements of this notice are accordingly effective immediately upon filing with the **Federal Register**. Additionally, to the extent that it is found that my determination is subject to the procedural requirements in 41 U.S.C. 1707, this determination is temporary, consistent with section 1707(e). And regardless of whether this determination is subject to the procedural requirements in 41 U.S.C. 1707, I am soliciting comment on all subjects of this determination, which would also be consistent with sections 1707(c) and (e), if those provisions applied.

B. Administrative Procedure Act

My determination is not subject to the procedural rulemaking requirements of the Administrative Procedure Act (APA).

As noted above, this determination is pursuant to a delegation from the President under 3 U.S.C. 301. When any agency acts pursuant to such a delegation, the agency ''stands in the President's shoes'' and its actions ''cannot be subject to judicial review under the APA.'' *NRDC* v. *State,* 658 F. Supp. 2d at 109 & n.5, 111.

Even if the APA were applicable, the notice-and-comment requirements of 5 U.S.C. 553 exempt ''a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.'' 5 U.S.C. 553(a)(2). This determination relates to procurement and contractors—*i.e.,* ''contracts'' under section 553(a)(2)—and is thus exempt from the APA's notice-and-comment requirements.

Moreover, even if the notice-and-comment requirements of 5 U.S.C. 553 were applicable, the good-cause exception is satisfied here. 5 U.S.C. 553(b)(3)(B) waives notice-and-comment requirements if ''the agency for good cause finds'' that compliance would be ''impracticable, unnecessary, or contrary to the public interest.'' Notice and comment is impracticable in situations where delay would result in harm. *See, e.g., Mack Trucks, Inc.* v. *EPA,* 682 F.3d 87, 93 (D.C. Cir. 2012). Applicable procedures are ''[i]mpracticable'' if ''the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings'' or negotiated rulemaking. *N.J., Dep't of Envtl. Prot.* v. *EPA,* 626 F.2d 1038, 1046 (D.C. Cir. 1980) (quoting S. Doc. No. 248, at 200 (1946)); *see also United States* v. *Cotton,* 760 F. Supp. 2d 116, 129 (D.D.C. 2011). Such ''good cause'' would also exempt an agency from the delayed effective

[18] Unlike the vaccination deadline for covered employees of Federal contractors, the vaccination deadline for Federal employees under Executive Order 14043 does not require alignment with private companies, because there is no subset of private companies also subject to Executive Order 14043. Thus, the exigencies of combatting the global pandemic require maintaining the current vaccination deadline for Federal employees of November 22, 2021.

date under 5 U.S.C. 553(d). For the reasons explained above, notice-and-comment rulemaking and a delayed effective date would be impracticable, because the resulting delay in the effective date would not provide Federal contractors and subcontractors sufficient time to ensure compliance in time for the January 18, 2022, vaccination deadline.

* * * * *

Shalanda Young,

Acting Director.

[FR Doc. 2021–24949 Filed 11–10–21; 4:15 pm]

BILLING CODE 3110–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m., Thursday, November 18, 2021.

PLACE: Due to the COVID–19 Pandemic, the meeting will be open to the public via live webcast only. Visit the agency's homepage (*www.ncua.gov*) and access the provided webcast link.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

1. Board Briefing, Share Insurance Quarterly Report.
2. NCUA's 2022–2026 Strategic Plan.
3. NCUA Rules and Regulations, Service Facilities.
4. Board Briefing, NCUA's Modernized Examination Tools.
5. Board Briefing, Update to NCUA's Response to the COVID–19 Pandemic.

CONTACT PERSON FOR MORE INFORMATION: Melane Conyers-Ausbrooks, Secretary of the Board, Telephone: 703–518–6304.

Melane Conyers-Ausbrooks,

Secretary of the Board.

[FR Doc. 2021–25032 Filed 11–12–21; 11:15 am]

BILLING CODE 7535–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Arts Advisory Panel Meetings

AGENCY: National Endowment for the Arts.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that 17 meetings of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference or videoconference.

DATES: See the **SUPPLEMENTARY INFORMATION** section for individual meeting times and dates. All meetings are Eastern time and ending times are approximate:

ADDRESSES: National Endowment for the Arts, Constitution Center, 400 7th St. SW, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Further information with reference to these meetings can be obtained from Ms. Sherry P. Hale, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; *hales@arts.gov,* or call 202/682–5696.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of September 10, 2019, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of title 5, United States Code.

The upcoming meetings are:

Our Town (review of applications): This meeting will be closed.

Date and time: December 2, 2021; 11:00 a.m. to 1:00 p.m.

Our Town (review of applications): This meeting will be closed.

Date and time: December 2, 2021; 2:30 p.m. to 4:30 p.m.

Arts Education (review of applications): This meeting will be closed.

Date and time: December 3, 2021; 11:30 a.m. to 1:30 p.m.

Arts Education (review of applications): This meeting will be closed.

Date and time: December 3, 2021; 2:30 p.m. to 4:30 p.m.

Our Town (review of applications): This meeting will be closed.

Date and time: December 3, 2021; 11:00 a.m. to 1:00 p.m.

Presenting and Multidisciplinary Works (review of applications): This meeting will be closed.

Date and time: December 6, 2021; 2:00 p.m. to 4:00 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 7, 2021; 11:30 a.m. to 1:30 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 7, 2021; 2:30 p.m. to 4:30 p.m.

Presenting and Multidisciplinary Works (review of applications): This meeting will be closed.

Date and time: December 7, 2021; 2:00 p.m. to 4:00 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 8, 2021; 11:30 a.m. to 1:30 p.m.

Presenting and Multidisciplinary Works (review of applications): This meeting will be closed.

Date and time: December 8, 2021; 2:00 p.m. to 4:00 p.m.

Arts Education (review of applications): This meeting will be closed.

Date and time: December 9, 2021; 1:30 p.m. to 3:30 p.m.

Local Arts Agencies (review of applications): This meeting will be closed.

Date and time: December 9, 2021; 1:00 p.m. to 3:00 p.m.

Local Arts Agencies (review of applications): This meeting will be closed.

Date and time: December 9, 2021; 3:30 p.m. to 5:30 p.m.

Presenting and Multidisciplinary Works (review of applications): This meeting will be closed.

Date and time: December 9, 2021; 2:00 p.m. to 4:00 p.m.

Folk and Traditional Arts (review of applications): This meeting will be closed.

Date and time: December 14, 2021; 1:00 p.m. to 3:00 p.m.

Folk and Traditional Arts (review of applications): This meeting will be closed.

Date and time: December 16, 2021; 1:00 p.m. to 3:00 p.m.

Dated: November 10, 2021.

Sherry P. Hale,

Staff Assistant, National Endowment for the Arts.

[FR Doc. 2021–24928 Filed 11–15–21; 8:45 am]

BILLING CODE 7537–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–201; NRC–2021–0175]

New York State Energy Research and Development Authority; Irradiated Nuclear Fuel Processing Plant; Western New York Nuclear Service Center

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued an

amendment to Facility Provisional Operating License No. CSF–1, issued to New York State Energy Research and Development Authority (NYSERDA), the licensee, for the provisional operation of the Irradiated Nuclear Fuel Processing Plant located at the Western New York Nuclear Service Center (WNYNSC), in Cattaraugus and Erie Counties, New York. The provisional operating license was amended to update the Radiation Protection Program for the Retained Premises of the Licensed Area for ''modernization'' and as requested by the licensee, to clarify the licensee's health and safety responsibilities as the sole licensee.

DATES: The amendment was issued on November 5, 2021.

ADDRESSES: Please refer to Docket ID NRC–2021–0175 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–2021–0175. 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, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's Public Document Room (PDR), Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. 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 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Amy Snyder, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–6822, email: *Amy.Snyder@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has issued Amendment No. 33 to Facility Provisional Operating License No. CSF–1, issued to NYSERDA (the license), which revised the Provisional Operating License for the WNYSC, Irradiated Nuclear Fuel Processing Plant (the facility), located in Cattaraugus and Erie Counties, New York. The amendment and related documents are listed in the Safety Evaluation enclosed with the amendment (ADAMS Access No. ML21245A246). The amendment was effective as of the date of its issuance.

The NRC has issued an amendment to Facility Provisional Operating License No. CSF–1. The amendment updates the Radiation Protection Program for the ''retained premises of the licensed area'' for modernization. In addition, as requested by the licensee, the license is amended to clarify the NYSERDA's, the sole licensee, health and safety and other responsibilities under the license. NYSERDA defines the ''retained premises of the licensed area'' as the area consisting of the WNYNSC, not including the U.S. Department of Energy (DOE) West Valley Demonstration Project (WVDP) premises and the State Licensed Disposal Area. Although portions of the site are actively being decommissioned by DOE under the West Valley Demonstration Project Act, 42 U.S.C. 2021a note, Public Law 96–868, 94 Stat. 1347 (1980) (WVDPA), NYSERDA retains responsibility for the portions of the site known as the ''retained premises.''

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in Chapter I of title 10 of the *Code of Federal Regulations* (10 CFR), which are set forth in the license amendment.

A notice of consideration of issuance of amendment and proposed no significant hazards consideration determination and opportunity for hearing in connection with this action was published in the **Federal Register** on March 10, 2021 (86 FR 13762). No request for a hearing or petition for leave to intervene was filed.

Under its regulations, the Commission may issue and make an amendment immediately effective, where it has determined that no significant hazards consideration is involved. The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that the amendment involves no significant hazards consideration. The basis for this determination is contained in the Safety Evaluation related to this action. Accordingly, as previously described, the amendment has been issued and made immediately effective.

The Commission prepared an environmental assessment (86 FR 60919), published on November 4, 2021, related to the action and has concluded that an environmental impact statement is not warranted because there will be no environmental impact attributable to the action beyond that which has been predicted and described in the Commission's final environmental statement for the facility dated November 1, 2021 (ML21245A012).

For further details with respect to this action, see the application for amendment dated March 11, 2020 (ML20076C310), as supplemented by letters dated October 28, 2020 (ML20311A200), July 15, 2021 (ML21202A212), September 10, 2021 (ADAMS Package Accession No. ML21281A019), and email dated October 12, 2021 (ML21286A001).

Dated: November 10, 2021.

For the Nuclear Regulatory Commission.

Bruce A. Watson,

Chief,Reactor Decommissioning Branch,Decommissioning, Uranium Recovery, andWaste Programs,Office of Nuclear Material Safety andSafeguards.

[FR Doc. 2021–24950 Filed 11–15–21; 8:45 am]

BILLING CODE 7590–01–P

PENSION BENEFIT GUARANTY CORPORATION

Privacy Act of 1974; System of Records

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of modified system of records.

SUMMARY: Pursuant to the Privacy Act of 1974 the Pension Benefit Guaranty Corporation (PBGC) is proposing changes to one system of records notice (SORN). PBGC is proposing to amend PBGC 21—Reasonable Accommodation Records. The amendment will expand the authorities for maintenance of the system, the purposes of the system, the categories of individuals covered by the system, the record source categories, and the records contained in the system, to include records of requests for accommodation based on sincerely held religious beliefs, practices, or observances.

DATES: The modified system of records described herein will become effective November 16, 2021.

ADDRESSES: You may submit written comments to PBGC by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the website instructions for submitting comments.
- *Email: reg.comments@pbgc.gov.* Refer to SORN in the subject line.
- *Mail or Hand Delivery:* Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005.

Commenters are strongly encouraged to submit public comments electronically. PBGC expects to have limited personnel available to process public comments that are submitted on paper through mail. Until further notice, any comments submitted on paper will be considered to the extent practicable.

All submissions must include the agency's name (Pension Benefit Guaranty Corporation, or PBGC) and reference this notice. Comments received will be posted without change to PBGC's website, *http://www.pbgc.gov,* including any personal information provided. Do not submit comments that include any personally identifiable information or confidential business information. Copies of comments may also be obtained by writing to Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005, or calling 202–326–4040 during normal business hours. (TTY users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4040.)

FOR FURTHER INFORMATION CONTACT: Shawn Hartley, Chief Privacy Officer, Pension Benefit Guaranty Corporation, Office of the General Counsel, 1200 K Street NW, Washington, DC 20005, 202–229–6321. For access to any of the PBGC's systems of records, contact D. Camilla Perry, Disclosure Officer, Office of the General Counsel, Disclosure Division, 1200 K Street NW, Washington DC 20005, or by calling 202–229–4040, or go to *https://www.pbgc.gov/about/policies/pg/privacy-at-pbgc/system-of-records-notices.*

SUPPLEMENTARY INFORMATION: PBGC is proposing to amend the authorities for maintenance of the system, purposes of the system, the categories of records contained in the system, the categories of individuals covered by the system, the record source categories, a citation in the Routine Uses section, a citation in the Record Access Procedures section, and a citation in the Contesting Records Procedures section of PBGC 21—Reasonable Accommodation Records.

PBGC is updating the Authority for Maintenance of the System by adding citations to ''42 U.S.C. 2000e *et seq.,* 42 U.S.C. 2000bb *et seq.*'' and adding Chapter 21 from Title 42 of the United States Code and Parts 1605 and 1614 from Title 29 of the Code of Federal Regulations. PBGC is expanding the one of the purposes of the system to allow PBGC to maintain records on individuals who requested or received reasonable accommodation by PBGC because of religious beliefs. PBGC is expanding the Categories of Records Contained in the System to include information concerning the individual's religious belief. PBGC is expanding the Categories of Individuals Covered by the System by adding the words ''or religious belief, practice or observance'' to include accommodation requests based on sincerely held religious beliefs and adding ''equal employment opportunity professionals'' to Record Source Categories. PBGC is also adding the citation to 29 CFR 4902.5 to the Contesting Records Procedures section and a **Federal Register** citation to PBGC's Prefatory Statement on Routine Uses to Routine Use 1. Additionally, upon review, it was noticed that the Routine Uses and the Record Access Procedures sections contained typographical errors. PBGC is amending the Privacy Act citation, changing it from 5 U.S.C. 522a(b) to 5 U.S.C. 552a(b) and fixing an erroneous reference from ''CRF'' to ''CFR.''

A report has been sent to Congress and the Office of Management and Budget for their evaluation.

For the convenience of the public, PBGC's amended system of records is published in full below with changes italicized.

Issued in Washington, DC.

Gordon Hartogensis,

Director, Pension Benefit Guaranty Corporation.

SYSTEM NAME AND NUMBER:

PBGC—21: Reasonable Accommodation Records

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005. (Records may be kept at an additional location as backup for continuity of operations.)

SYSTEM MANAGER(S) AND ADDRESS:

Reasonable Accommodations Coordinator, Human Resources Department, PBGC, 1200 K Street NW, Washington, DC 20005.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

29 U.S.C. 1302; 44 U.S.C. 3101; 5 U.S.C. 301; 29 U.S.C. 701 *et seq.;* 29 U.S.C. 791; 42 U.S.C. 12101 *et seq.; 42 U.S.C. 2000e et seq.; 42 U.S.C. 2000bb;* 42 U.S.C. Ch. *21,* 126; 29 CFR Part*s 1605, 1614,* 1630; Executive Order 13164 (July 26, 2000); and Executive Order 13548 (July 26, 2010).

PURPOSE(S) OF THE SYSTEM:

The purposes of this system are: (1) To allow PBGC to collect and maintain records on prospective, current, and former employees with disabilities *or sincerely held religious beliefs, practices, or observances* who requested or received reasonable accommodation by PBGC; (2) to track and report the processing of requests for reasonable accommodation PBGC-wide to comply with applicable law and regulations; and (3) to maintain the confidentiality of medical *or religious* information submitted by or on behalf of applicants or employees requesting reasonable accommodation.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Prospective, current, and former employees of PBGC who request and/or receive a reasonable accommodation for a disability *or religious belief, practice, or observance* authorized individuals or representatives (*e.g.,* family members, union representatives, or attorneys) who submit a request for a reasonable accommodation on behalf of a prospective, current, or former employee.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name and employment information of current or prospective employee needing an accommodation; requester's name and contact information (if different than the employee who needs an accommodation); date request was initiated; information concerning the nature of the disability *or religious belief, practice, or observance* and the need for accommodation, including appropriate medical *or other* documentation; occupational series; pay grade; essential duties of the position; details of the accommodation request, such as: Type of accommodation requested, how the requested accommodation would assist in job *or allow job* performance *while accommodating the disability or religious belief, practice, or observance,*

the sources of technical assistance consulted in trying to identify alternative reasonable accommodation, any additional information provided by the requester relating to the processing of the request, whether the request was approved or denied, whether the accommodation was approved for a trial period; and, documentation between the employee and his/her supervisor(s) regarding the accommodation.

RECORD SOURCE CATEGORIES:

Subject individuals; individual making the request (if different than the subject individuals); medical *and equal employment opportunity* professionals; and the subject individuals' supervisor(s).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information about covered individuals may be disclosed without consent as permitted by the Privacy Act of 1974, 5 U.S.C. *552*a(b), and:

1. General Routine Uses G1 through G14 apply to this system of records (see Prefatory Statement of General Routine Uses *at 83 FR 6247 (Feb. 13, 2018)*).

2. A record from this system may be disclosed to physicians or other medical professionals to provide them with or obtain from them the necessary medical documentation and/or certification for reasonable accommodation.

3. A record from this system may be disclosed to another federal agency or commission with responsibility for labor or employment relations or other issues, including equal employment opportunity and reasonable accommodation issues, when that agency or commission has jurisdiction over reasonable accommodation issues.

4. A record from this system may be disclosed to the Office of Management and Budget (OMB), Department of Labor (DOL), Office of Personnel Management (OPM), Equal Employment Opportunity Commission (EEOC), or Office of Special Counsel (OSC) to obtain advice regarding statutory, regulatory, policy, and other requirements related to reasonable accommodation.

5. A record from this system may be disclosed to appropriate third-parties contracted by the Agency to facilitate mediation or other dispute resolution procedures or programs.

6. A record from this system may be disclosed to the Department of Defense (DOD) for purposes of procuring assistive technologies and services through the Computer/Electronic Accommodation Program in response to a request for reasonable accommodation.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained manually in paper and/or electronic form (including computer databases or discs). Records may also be maintained on back-up tapes, or on a PBGC or a contractor-hosted network.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by any one or more of the following: Employee name or assigned case number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained and destroyed in accordance with the National Archives and Record Administration's (NARA) Basic Laws and Authorities (44 U.S.C. 3301, *et seq.*) or a PBGC records disposition schedule approved by NARA. Records existing on paper are destroyed beyond recognition.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

PBGC has established security and privacy protocols that meet the required security and privacy standards issued by the National Institute of Standards and Technology (NIST). Records are maintained in a secure, password protected electronic system that utilizes security hardware and software to include multiple firewalls, active intruder detection, and role-based access controls. PBGC has adopted appropriate administrative, technical, and physical controls in accordance with PBGC's security program to protect the confidentiality, integrity, and availability of the information, and to ensure that records are not disclosed to or accessed by unauthorized individuals.

Electronic records are stored on computer networks, which may include cloud-based systems, and protected by controlled access with Personal Identity Verification (PIV) cards, assigning user accounts to individuals needing access to the records and by passwords set by authorized users that must be changed periodically.

RECORD ACCESS PROCEDURES:

Individuals, or third parties with written authorization from the individual, wishing to request access to their records in accordance with 29 CFR 4902.4 or to amend records pertaining to themselves in accordance with 29 CFR 4902.5, should submit a written request to the Disclosure Officer, PBGC, 1200 K Street NW, Washington, DC 20005, providing their name, address, date of birth, and verification of their identity in accordance with 29 CFR 4902.3(c).

CONTESTING RECORD PROCEDURES:

Individuals, or third parties with written authorization from the individual, wishing to *amend, in accordance with 29 CFR 4902.5,* their records must submit a written request identifying the information they wish to correct in their file, in addition to following the requirements of the Record Access Procedure above

NOTIFICATION PROCEDURES:

Individuals, or third parties with written authorization from the individual, wishing to learn whether this system of records contains information about them should submit a written request to the Disclosure Officer, PBGC, 1200 K Street NW, Washington, DC 20005, providing their name, address, date of birth, and verification of their identity in accordance with 29 CFR 4902.3(c).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

PBGC—21, Reasonable Accommodation Records (last published at 83 FR 6271 (February 13, 2018)).

[FR Doc. 2021–24905 Filed 11–15–21; 8:45 am]

BILLING CODE 7709–02–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2022–19 and CP2022–21]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 17, 2021.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2022–19 and CP2022–21; *Filing Title:* USPS Request to Add Priority Mail Contract 728 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 9, 2021; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Gregory Stanton; *Comments Due:* November 17, 2021.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2021–24932 Filed 11–15–21; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93546; File No. SR–CboeBZX–2021–075]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Reflect a Modification to the Permitted Components of the Tracking Baskets of the Invesco Real Assets ESG ETF and Invesco US Large Cap Core ETF

November 9, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 2, 2021, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. 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

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') proposes to reflect an amendment to the Reference Order relied upon by the Invesco Real Assets ESG ETF and Invesco US Large Cap Core ESG ETF, shares of which are listed and traded on the Exchange under BZX Rule 14.11(m).

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, 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 adopted BZX Rule 14.11(m) for the purpose of permitting the listing and trading, or pursuant to unlisted trading privileges (''UTP''), of Tracking Fund Shares, which are securities issued by an actively managed open-end management investment company.[3] Exchange Rule 14.11(m)(2)(A) requires the Exchange to file separate proposals under Section 19(b) of the Act before listing and trading any series of Tracking Fund Shares on the Exchange. Pursuant to this provision, the Exchange submitted proposals to list and trade shares (''Shares'') of Tracking Fund Shares of the following funds under BZX Rule 14.11(m): Invesco Real Assets ESG ETF and Invesco US Large Cap Core ESG

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 88887 (May 15, 2020), 85 FR 30990 (May 21, 2020) (SR–CboeBZX–2019–107) (Notice of Filing of Amendment No. 5 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 5, to Adopt Rule 14.11(m), Tracking Fund Shares, and to List and Trade Shares of the Fidelity Blue Chip Value ETF, Fidelity Blue Chip Growth ETF, and Fidelity New Millennium ETF (''Approval Order'')). Rule 14.11(m)(3)(A) provides that ''[t]he term ''Tracking Fund Share'' means a security that (i) represents an interest in an investment company registered under the Investment Company Act of 1940 (''Investment Company'') organized as an open-end management investment company, that invests in a portfolio of securities selected by the Investment Company's investment adviser consistent with the Investment Company's investment objectives and policies; (ii) is issued in a specified aggregate minimum number in return for a deposit of a specified Tracking Basket and/or a cash amount with a value equal to the next determined net asset value; (iii) when aggregated in the same specified minimum number, may be redeemed at a holder's request, which holder will be paid a specified Tracking Basket and/or a cash amount with a value equal to the next determined net asset value; and (iv) the portfolio holdings for which are disclosed within at least 60 days following the end of every fiscal quarter. Rule 14.11(m)(3)(E) provides that ''[t]he term ''Tracking Basket'' means the identities and quantities of the securities and other assets included in a basket that is designed to closely track the daily performance of the Fund Portfolio, as provided in the exemptive relief under the Investment Company Act of 1940 applicable to a series of Tracking Fund Shares.''

ETF (each, a ''Fund'' and, together the ''Funds'').[4]

Among others, Invesco Actively Managed Exchange-Traded Fund Trust (the ''Issuer''), issued a second amended and restated application for an order under Section 6(c) of the 1940 Act for exemptions from various provisions of the 1940 Act and rules thereunder (the ''Application'').[5] On October 27, 2020, the Commission issued an order (the ''Prior Exemptive Order'') under the 1940 Act granting the exemptions requested in the Application.[6] The relief in the Prior Exemptive Order incorporates by reference terms and conditions of the same relief of a previous order granting the same relief sought by applicants, as that order may be amended from time to time (the ''Reference Order'').[7]

Under the Prior Exemptive Order, the Funds are required to publish a basket of securities and cash that, while different from the Fund's portfolio, is designed to closely track its daily performance (*i.e.,* the Tracking Basket). The Prior Exemptive Order provided that the Tracking Basket will solely consist of a combination of (i) select recently disclosed portfolio holdings (''Strategy Components''); (ii) liquid U.S. exchange-traded funds (''ETFs'') that convey information about the types of instruments (that are not otherwise fully represented by the Strategy Components) in which a Fund invests (''Representative ETFs''); and (iii) cash and cash equivalents. Exchange Rule 14.11(m)(4)(B)(iii)(c) provides that the Exchange will consider the suspension of trading in and will commence delisting proceedings for a series of Tracking Fund Shares pursuant to Rule 14.12 if, among other things, the Exchange is aware that the Investment Company is not in compliance with the conditions of any exemptive order or no-action relief granted by the Commission or the Commission staff under the 1940 Act to the Investment Company with respect to the series of Tracking Funds Shares. On August 5, 2021, the Commission issued an amended order to the Reference Order that, among other things, permits the Issuer to include select securities from which a Fund's investment are selected such as a broad-based market index (''Investment Universe'') in the Fund's Tracking Basket (the ''Amended Reference Order'').[8] The Funds will comply with this condition of the Amended Reference Order and the Exchange is updating the listing rule for the Shares accordingly. Except for the change noted above, all other representations made in the rule filing remain unchanged and will continue to constitute continuing listing requirements for the Funds. The Funds will also continue to comply with the requirements of Rule 14.11(m).

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[9] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [10] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, 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 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.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest. The proposed revision is intended to reflect the change in the Amended Reference Order that permits the Issuer to include select securities from the Fund's Investment Universe in the Fund's Tracking Basket. The proposed rule change would permit the Funds to operate consistent with the Prior Exemptive Order, which incorporates the Reference Order that may be amended from time to time. Furthermore, Exchange Rule 14.11(m)(4)(B)(iii)(c) provides that the Exchange will consider the suspension of trading in and will commence delisting proceedings for a series of Tracking Fund Shares pursuant to Rule 14.12 if, among other things, the Exchange is aware that the Investment Company is not in compliance with the conditions of any exemptive order or no-action relief granted by the Commission of the Commission Staff under the 1940 Act to the Investment Company with respect to the series of Tracking Funds Shares. By clearly identifying the change in the committed components of each Funds' Tracking Basket, the proposed Rule change will assist the Exchange in complying this aspect of the listing rule, as modified, consistent with section 6(b)(1) of the Act.[11] Except for the changes noted above, all other representations made in the respective rule filings remain unchanged and, as noted, will continue to constitute continuing listing requirements for the Funds.

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 that is not necessary or appropriate in furtherance of the purpose of the Act. As noted, the purpose of the filing is to reflect an amendment to the Reference Order governing the listing and trading of these Funds. As noted, the effect of this filing is to allow an adjustment to the components of the Tracking Baskets for each of the Funds. The Exchange believes this will not impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [12] and subparagraph (f)(6) of Rule 19b–4 thereunder.[13]

[4] *See* Securities Exchange Act Release No. 90686 (December 16, 2020) 85 FR 83657 (December 22, 2020) (SR–CboeBZX–2020–090).

[5] *See* File No. 812–15141, dated September 30, 2020.

[6] *See* Investment Company Act Release No. 34076, October 27, 2020.

[7] The Reference Order refers to the Fidelity Beach Street Trust, et al., Investment Company Act Rel. Nos. 33683 (Nov. 14, 2019) (notice) and 33712 (Dec. 10, 2019) (order).

[8] *See* Investment Company Act Release No. 34350, August 5, 2021.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78f(b)(1).

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

A proposed rule change filed under Rule 19b–4(f)(6) [14] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[15] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may take effect upon filing. The Exchange states that the proposed rule change raises no novel regulatory issues because the Funds will continue to comply with the requirements of BZX Rule 14.11(m). The Exchange also notes that a similar proposal to amend the listing rules of other shares that BZX also lists and trades pursuant to Rule 14.11(m) is currently in effect.[16] For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposal operative upon filing.[17]

At any time within 60 days of the filing of such 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeBZX–2021–075 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–2021–075. 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 (*http://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 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange.

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–CboeBZX–2021–075 and should be submitted on or before December 7, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24896 Filed 11–15–21; 8:45 am]

BILLING CODE 8011–01–P

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] *See* Securities and Exchange Act No. 92946 (September 13, 2021) 86 FR 51941 (September 17, 2021) (SR–CboeBZX–2021–060).

[17] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold an Open Meeting on Wednesday, November 17, 2021 at 11:00 a.m.

PLACE: The meeting will be webcast on the Commission's website at *www.sec.gov.*

STATUS: This meeting will begin at 11:00 a.m. (ET) and will be open to the public via webcast on the Commission's website at *www.sec.gov.*

MATTERS TO BE CONSIDERED:

1. The Commission will consider whether to adopt amendments to the proxy rules relating to the use of universal proxy cards and related disclosures in director elections.

2. The Commission will consider whether to propose amendments to the proxy rules governing proxy voting advice.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: November 10, 2021.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2021–25030 Filed 11–12–21; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93545; File No. SR–NYSE–2021–65]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List

November 9, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 1, 2021, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the 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] 15 U.S.C. 78a.

[3] 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 to[sic] amend its Price List to (1) eliminate the underutilized additional credits for member organizations that add liquidity in Tape B and C Securities when qualifying for certain non-tier and tiered credits by adding liquidity in Tape A Securities; (2) eliminate the underutilized Adding Tier for Non-Displayed Providers in Tape A Securities; and (3) revise the requirements to qualify for the Tier 5 Adding Credit in Tape A Securities. The Exchange proposes to implement the rule change on November 1, 2021. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, 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 self-regulatory organization 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 those 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 parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Price List to (1) eliminate the underutilized additional credits for member organizations that add liquidity in Tape B and C Securities when qualifying for certain non-tier and tiered credits by adding liquidity in Tape A Securities; (2) eliminate the underutilized Adding Tier for Non-Displayed Providers in Tape A Securities; and (3) revise the requirements to qualify for the Tier 5 Adding Credit in Tape A Securities.

The proposed revision to the Tier 5 Adding Credit responds to the current competitive environment where order flow providers have a choice of where to direct liquidity-providing orders by offering further incentives for member organizations to send additional displayed liquidity to the Exchange.

The Exchange proposes to implement the rule change on November 1, 2021.

Current Market and Competitive Environment

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [4]

As the Commission itself has recognized, the market for trading services in NMS stocks has become ''more fragmented and competitive.'' [5] Indeed, equity trading is currently dispersed across 16 exchanges,[6] 31 alternative trading systems,[7] and numerous broker-dealer internalizers and wholesalers. Based on publicly-available information, no single exchange has more than 18% of the market.[8] Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, the Exchange's share of executed volume of equity trades in Tapes A, B and C securities is less than 12%.[9]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. With respect to non-marketable order flow that would provide displayed liquidity on an Exchange, member organizations can choose from any one of the numerous currently operating registered exchanges to route such order flow. Accordingly, competitive forces constrain exchange transaction fees that relate to orders that would provide liquidity on an exchange.

Proposed Rule Change

The Exchange proposes to eliminate certain underutilized additional credits for adding liquidity in Tape B and C Securities and the underutilized Adding Tier for Non-Displayed Providers in Tape A Securities, as follows.

Underutilized Additional Credits

Member organizations adding liquidity in Tape A Securities and meeting all of the requirements of the Non-Tier Adding Credit, the Tier 1 Adding Credit, the Tier 2 Adding Credit, the Tier 3 Adding Credit, the Tier 4 Adding Credit, the Tier 5 Adding Credit, the Tier 6 Adding Credit, the Step Up Tier 1 Adding Credit, the Step Up Tier 2 Adding Credit and the Step Up Tier 4 Adding Credit are currently eligible for an additional credit of $0.0001 per share (under the Non-Tier Adding Credit, Tier 3 Adding Credit, Tier 4 Adding Credit, Tier 5 Adding Credit, Tier 6 Adding Credit, and Step Up Tier 4 Adding Credit) or $0.0005 per share (under the Tier 1 Adding Credit, Tier 2 Adding Credit, Step Up Tier 1 Adding Credit, and Step Up Tier 2 Adding Credit) if the member organization also adds a specified amount of liquidity, excluding liquidity added as an Supplemental Liquidity Provider (''SLP''), in Tapes B and C Securities.

The Exchange proposes to eliminate and remove these additional credits from the Non-Tier Adding Credit, Tier 1 Adding Credit, Tier 2 Adding Credit, Tier 3 Adding Credit, Tier 4 Adding Credit, Tier 5 Adding Credit, Tier 6 Adding Credit, Step Up Tier 1 Adding Credit, Step Up Tier 2 Adding Credit and Step Up Tier 4 Adding Credit sections of the Price List. The additional credit has been underutilized by member organizations insofar as no member organization qualified for an additional credit year to date in any of the non-tier or tiers in which it is offered. As such, Exchange does not anticipate that any member organization in the near future would qualify for the additional credits that are the subject of this proposed rule change.

Underutilized Adding Tier for Non-Displayed Providers in Tape A Securities

Under the current Adding Tier for Non-Displayed Providers, the Exchange provides credits in Tape A securities for all orders, other than MPL Orders, from

---

[4] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS'').

[5] *See* Securities Exchange Act Release No. 51808[sic], 84FR 5202, 5253 (February 20, 2019) (File No. S7–05–18) (Transaction Fee Pilot for NMS Stocks Final Rule) (''Transaction Fee Pilot'').

[6] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[7] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[8] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[9] *See id.*

qualifying member organizations that have at least

• an average daily trading volume (''ADV'') that adds liquidity to the Exchange during the billing month (''Adding ADV'') of 0.35% of Tape A consolidated ADV (''Tape A CADV''), excluding any liquidity added by a Designated Market Maker (''DMM'');[10] and

• Adding ADV of Non-Displayed Limit Orders of at least 4 million shares; and

• 35% of the Member Organization's Total Adding ADV is comprised of Non-Displayed Limit Orders.

A member organization that meets the above requirements receives a credit of $0.0023 per share ($0.0006 per share for Non-Displayed Limit Orders) if the member organization has an Adding ADV of at least 0.35% of Tape A CADV or a credit of $0.0026 per share ($0.0007 per share for Non-Displayed Limit Orders) if the member organization has Adding ADV of at least 0.45% of Tape A CADV.

In addition, Member Organizations meeting the above requirements and adding liquidity, excluding liquidity added as an SLP, in Tapes B and C Securities of at least 0.20% of Tape B and Tape C CADV combined will receive an additional $0.00005 per share.

The Exchange proposes to eliminate the Adding Tier for Non-Displayed Providers in its entirety and remove it from the Price List. The tier, including the additional $0.00005 per share credit, has been underutilized by member organizations insofar as no member organization has qualified for the tier since its introduction in April 2021. As such, Exchange does not anticipate any member organization in the near future would qualify for the credit that is the subject of this proposed rule change.

Alternative Qualification for Tier 5 Adding Credit

In response to the competitive environment described above, the Exchange has established incentives for its member organizations who submit orders that provide liquidity on the Exchange. The proposed fee change is also designed to attract additional order flow to the Exchange by incentivizing member organizations to submit additional displayed liquidity to the Exchange.

Under the current Tier 5 Adding Credit, the Exchange provides a $0.0017 credit in Tape A securities for orders, other than MPL and Non-Display Reserve orders, that add liquidity to the Exchange where a member organization's Adding ADV, excluding liquidity added as an SLP and as a DMM, is at least 0.29% of NYSE CADV. Further, member organizations that meet the above requirements and add liquidity, excluding liquidity added as an SLP, in Tape B and C Securities of at least 0.20% of Tape B and Tape C CADV combined, would receive an additional $0.0001 per share. As discussed above, the Exchange proposes to delete this additional credit as underutilized.

The Exchange further proposes to provide an alternative way for member organizations to qualify for the Tier 5 Adding Credit. As proposed, as an alternative to where a member organization's Adding ADV, excluding liquidity added as an SLP and as a DMM, is at least 0.29% of NYSE CADV, member organizations that have an Adding ADV, excluding liquidity added as an SLP and as a DMM, of at least 0.125% of NYSE CADV and two times more than the Member Organization's Adding ADV in Tape A Securities in Q1 2021[11] as a percentage of NYSE CADV would also qualify for the $0.0017 credit.

The Exchange believes that the alternative way to qualify for the Tier 5 Adding Credit will incentivize greater participation from member organizations to increase liquidity-providing orders in the Tape A securities they send to the Exchange to qualify for the Tier 5 Adding Credit, which would support the quality of price discovery on the Exchange and provide additional liquidity for incoming orders. As noted above, the Exchange operates in a competitive environment, particularly as it relates to attracting non-marketable orders, which add liquidity to the Exchange. The Exchange does not know how much order flow member organizations choose to route to other exchanges or to off-exchange venues. Based on the profile of liquidity-adding firms generally, the Exchange believes that additional member organizations could qualify for the tier under the revised qualification criteria if they choose to direct order flow to, and increase quoting on, the Exchange. However, without having a view of member organization's activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any member organization directing orders to the Exchange in order to qualify for the new tier.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[13] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Change Is Reasonable

Elimination of Underutilized Credits and Adding Tier in Tape A Securities

The Exchange believes that the proposed elimination of the underutilized additional credits for member organizations that add liquidity in Tape B and C Securities when qualifying for certain non-tier and tiered credits by adding liquidity in Tape A Securities is reasonable because member organizations have underutilized this incentive. No member organization has qualified for an additional credit year to date in any of the non-tier or tiers in which it is offered. The Exchange does not anticipate any member organization in the near future qualifying for the rebate that is the subject of this proposed rule change. Similarly, the Exchange believes that the proposed elimination of the Adding Tier for Non-Displayed Providers in Tape A Securities is reasonable. No member organization has qualified for the rebate since it was adopted in April 2021, and the Exchange does not anticipate any member organization in the near future qualifying for the tier. The Exchange believes it is reasonable to eliminate credits when such incentives become underutilized. The Exchange also believes eliminating underutilized incentives would add clarity and transparency to the Price List.

Alternative Qualification for Tier 5 Adding Credit in Tape A Securities

As discussed above, the Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market

[10] Footnote 2 to the Price List defines ADV as ''average daily volume'' and ''Adding ADV'' as ADV that adds liquidity to the Exchange during the billing month. CADV is defined in footnote * of the Price List.

[11] The current Tier 6 Adding Credit uses ''1Q'', which the Exchange proposes to change to ''Q1'' for consistency and clarity.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4) & (5).

forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [14] While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [15]

Given the current competitive environment, the Exchange believes that the proposed revision to the requirements for member organizations to qualify for Tier 5 Adding Credit represents a reasonable attempt to attract additional order flow to the Exchange. Specifically, the Exchange believes that the proposed revision is reasonable because it would provide further incentives for member organizations to route additional liquidity-providing orders to a public exchange, thereby promoting price discovery and transparency and enhancing order execution opportunities for member organizations. All member organizations would benefit from the greater amounts of liquidity that will be present on the Exchange, which would provide greater execution opportunities.

As noted above, the Exchange operates in a competitive environment, particularly as relates to attracting non-marketable orders, which add liquidity to the Exchange. The Exchange believes that an alternative method to qualify for the tier will provide greater incentives for member organizations to add more liquidity to the Exchange. The Exchange does not know how much order flow member organizations choose to route to other exchanges or to off-exchange venues. Based on the profile of liquidity-adding firms generally, the Exchange believes that additional member organizations could qualify for the tier under the revised qualification criteria if they choose to direct order flow to, and increase quoting on, the Exchange. However, without having a view of member organizations' activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any additional member organizations directing orders to the Exchange in order to qualify for the Tier 5 Adding Credit.

The Proposal Is an Equitable Allocation of Fees

Elimination of Underutilized Credits and Adding Tier in Tape A Securities

The Exchange believes the proposal equitably allocates fees among its market participants because the underutilized additional credits and Adding Tier the Exchange proposes to eliminate would be eliminated in their entirety, and would no longer be available to any member organization in any form. Similarly, the Exchange believes the proposal equitably allocates fees among its market participants because elimination of the underutilized credits would apply to all similarly-situated member organizations on an equal basis. All such member organizations would continue to be subject to the same fee structure, and access to the Exchange's market would continue to be offered on fair and nondiscriminatory terms.

Alternative Qualification for Tier 5 Adding Credit in Tape A Securities

The Exchange believes the proposed rule change equitably allocates its fees among its market participants. The proposed change would continue to encourage member organizations to submit additional liquidity to the Exchange and execute orders on the Exchange, thereby contributing to robust levels of liquidity, to the benefit of all market participants.

The Exchange believes that providing an additional way to qualify for the Tier 5 Adding Credit would encourage the submission of additional liquidity to the Exchange, thereby providing customers with a higher quality venue for price discovery, liquidity, competitive quotes and price improvement. The proposed change will thereby encourage the submission of additional liquidity to a national securities exchange, thus promoting price discovery and transparency and enhancing order execution opportunities for member organizations from the substantial amounts of liquidity present on the Exchange. All member organizations would benefit from the greater amounts of liquidity that will be present on the Exchange, which would provide greater execution opportunities.

The proposal neither targets nor will it have a disparate impact on any particular category of market participant. Specifically, the Exchange believes that the proposal constitutes an equitable allocation of fees because all similarly situated member organizations would be eligible for the same credits if they meet the revised requirements for the tier. As to those member organizations that do not presently qualify for the adding liquidity credit, the proposal will not adversely impact their existing pricing or their ability to qualify for other credits provided by the Exchange.

The Proposal Is Not Unfairly Discriminatory

Elimination of Underutilized Credits and Adding Tier in Tape A Securities

The Exchange believes that the proposal is not unfairly discriminatory. The proposal is not unfairly discriminatory because it neither targets nor will it have a disparate impact on any particular category of market participant. The Exchange believes that the proposal is not unfairly discriminatory because the proposed elimination of the underutilized additional credits and Adding Tier would affect all similarly-situated market participants on an equal and non-discriminatory basis. The Exchange believes that eliminating credits that are underutilized and ineffective would no longer be available to any member organization on an equal basis. The Exchange also believes that the proposed change would protect investors and the public interest because the deletion of underutilized fees would make the Price List more accessible and transparent and facilitate market participants' understanding of the fees charged for services currently offered by the Exchange.

Alternative Qualification for Tier 5 Adding Credit in Tape A Securities

The Exchange believes that the proposal is not unfairly discriminatory. In the prevailing competitive environment, member organizations are free to disfavor the Exchange's pricing if they believe that alternatives offer them better value.

The proposed changes to the Tier 5 Adding Credit are not unfairly discriminatory because the alternate requirements to achieve the credit would be applied to all similarly situated member organizations and other market participants, who would all be subject to the same modified requirements to qualify for the tier and the same credits on an equal basis. For the same reason, the proposal neither targets nor will it have a disparate impact on any particular category of market participant. Accordingly, no

[14] *See* Regulation NMS, *supra* note 4, at 37499.

[15] *See* Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

member organization already operating on the Exchange would be disadvantaged by this allocation of fees. Further, the Exchange believes the proposal would incentivize member organizations to send more orders to the Exchange to qualify for higher credits.

The Exchange believes that the proposed changes would not permit unfair discrimination among member organizations because the tiered rates are available equally to all member organizations. As described above, in today's competitive marketplace, order flow providers have a choice of where to direct liquidity-providing order flow, and the Exchange believes there are additional member organizations that could qualify if they chose to direct their order flow to the Exchange. Finally, the submission of orders to the Exchange is optional for member organizations in that they could choose whether to submit orders to the Exchange and, if they do, the extent of its activity in this regard.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[16] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the proposal relates to the elimination of an underutilized credits and an adding tier and, as such, would not have any impact on intra- or inter-market competition because the proposed change is solely designed to accurately reflect the services that the Exchange currently offers, thereby adding clarity to the Price List.

In accordance with Section 6(b)(8) of the Act,[17] the Exchange further believes that the proposed rule change offering an alternative method to qualify for the Tier 5 Adding Credit would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional liquidity and order flow to a public exchange, thereby enhancing order execution opportunities for member organizations. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [18]

Intramarket Competition. The proposed change is designed to attract additional order flow to the Exchange. As described above, the Exchange believes that the proposed change would provide additional incentives for market participants to route liquidity-providing orders to the Exchange. Greater liquidity benefits all market participants on the Exchange by providing more trading opportunities and encourages member organizations to send orders, thereby contributing to robust levels of liquidity, which benefits all market participants on the Exchange. The current and proposed credits would be available to all similarly-situated market participants, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchanges and off-exchange venues if they deem fee levels at those other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and off-exchange venues. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition.

The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [19] of the Act and subparagraph (f)(2) of Rule 19b–4 [20] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such 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 under Section 19(b)(2)(B) [21] of the Act to determine whether the proposed rule change 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2021–65 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–NYSE–2021–65. 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 (*http://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

[16] 15 U.S.C. 78f(b)(8).

[17] 15 U.S.C. 78f(b)(8).

[18] Regulation NMS, 70 FR at 37498–99.

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(2).

[21] 15 U.S.C. 78s(b)(2)(B).

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 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2021–65, and should be submitted on or before December 7, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24897 Filed 11–15–21; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Docket No. SBA–2020–0048]

Termination of Nonmanufacturer Rule Class Waiver

AGENCY: U.S. Small Business Administration.

ACTION: Notification of intent to terminate the class waiver to the Nonmanufacturer Rule for radiology equipment.

SUMMARY: The U.S. Small Business Administration (SBA) is considering terminating a class waiver of the Nonmanufacturer Rule (NMR) for irradiation apparatus manufacturing, computerized axial tomography (CT/CAT) scanners manufacturing; CT/CAT (computerized axial tomography) scanners manufacturing; fluoroscopes manufacturing; fluoroscopic X-ray apparatus and tubes manufacturing; generators, X-ray, manufacturing; irradiation equipment manufacturing; X-ray generators manufacturing; and X-ray irradiation equipment manufacturing under manufacturing categorized under North American Industry Classification System (NAICS) code 334517 and Product Service Code (PSC) 6525.

[22] 17 CFR 200.30–3(a)(12).

DATES: Comments and source information must be submitted on or before xx/xx/xxxx.

ADDRESSES: You may submit comments and source information via the Federal Rulemaking Portal at *https://www.regulations.gov* under Docket ID SBA–2020–1148]. 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 Carol Hulme, Attorney Advisor, Office of Government Contracting, U.S. Small Business Administration, 409 Third 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 a final determination as to whether the information will be published.

FOR FURTHER INFORMATION CONTACT: Carol Hulme, Attorney Advisor, by telephone at 202–205–6347 or by email at *Carol-Ann.Hulme@sba.gov.*

SUPPLEMENTARY INFORMATION: An awardee of a Federal small business set-aside contract valued over $250,000.00, service-disabled veteran-owned small business contract, HUBZone contract, women-owned small business contract, or 8(a) contract must provide its own product or that of a small business manufacturer unless a waiver is in place. If the above-identified class waiver is terminated, small businesses will no longer be authorized to provide the product of any manufacturer regardless of size on the identified items, unless a Federal contracting officer obtains an individual waiver to the NMR.

Section 8(a)(17) and 46 of the Small Business Act (Act), 15 U.S.C. 637(a)(17) and 657s, and SBA's implementing regulations, found at 13 CFR 121.406(b), require that recipients of Federal supply contracts issued as a small business set-aside (except as stated below), service-disabled veteran-owned small business (SDVO SB) set-aside or sole source contract, Historically Underutilized Business Zone (HUBZone) set-aside or sole source contract, WOSB (women-owned small business) or economically disadvantaged women-owned small business (EDWOSB) set-aside or sole source contract, 8(a) set-aside or sole source contract, partial set-aside, or set aside of an order against a multiple award contract provide the product of a small business manufacturer or processor if the recipient is other than the actual manufacturer or processor of the product. This requirement is commonly referred to as the Nonmanufacturer Rule (NMR). 13 CFR 121.406(b). Note that the NMR does not apply to small business set-aside acquisitions with an estimated value between the micro-purchase threshold and the simplified acquisition threshold but continues to apply to socioeconomic categories over the micropurchase threshold.

Sections 8(a)(17)(B)(iv)(II) and 46(a)(4)(B) of the Act authorize SBA to waive the NMR for a ''class of products'' for which there are no small business manufacturers or processors available to participate in the Federal market. The SBA defines ''class of products'' based on a combination of (1) the six-digit NAICS code, (2) the four-digit PSC, and (3) a description of the class of products. As implemented in SBA's regulations at 13 CFR 121.1202(c), in order to be considered available to participate in the Federal market for a class of products, a small business manufacturer must have submitted a proposal for a contract solicitation or been awarded a contract to supply the class of products within the last 24 months.

In accordance with the SBA's regulations at 13 CFR 121.1204(a)(7), SBA will periodically review existing class waivers to the NMR to determine whether small business manufacturers or processors have become available to participate in the Federal market. Upon receipt of information that such a small business manufacturer or processor exists, the SBA will announce its intent to terminate the NMR waiver for a class of products. 13 CFR 121.1204(a)(7)(ii). Unless public comment reveals no small business exists for the class of products in question, SBA will publish a Final Notice of Termination in the **Federal Register**.

On October 31, 2007, the SBA published in the **Federal Register** a notice of intent to waiver the Nonmanufacturer Rule for Irradiation Apparatus Manufacturing (X-Ray Equipment and Supplies). The comments submitted in response failed to establish the existence of a small business manufacturer of these products. As such, on December 26, 2007, after the comment and notice period passed, SBA issued a class waiver for those products effective January 10, 2008. That notice can be found at 77 FR 73057.

On April 20, 2020, SBA received a request to terminate the previously issued waiver. The requester provided information that established the existence of a small business manufacturer of the identified products. Thus SBA is proposing to terminate the class waiver for irradiation apparatus manufacturing, computerized axial

tomography (CT/CAT) scanners manufacturing; CT/CAT (computerized axial tomography) scanners manufacturing; fluoroscopes manufacturing; fluoroscopic X-ray apparatus and tubes manufacturing; generators, X-ray, manufacturing; irradiation equipment manufacturing; X-ray generators manufacturing; and X-ray irradiation equipment manufacturing under NAICS code 334517 and PSC 6525. The public is invited to comment or provide source information on the proposed termination of the NMR waiver for these products.

More information on the NMR and class waivers can be found at *https://www.sba.gov/contracting/contracting-officials/non-manufacturer-rule/non-manufacturer-waivers.*

David Wm. Loines,

Director, Office of Government Contracting.

[FR Doc. 2021–24971 Filed 11–15–21; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Delegations of Authority

AGENCY: U.S. Small Business Administration.

ACTION: Notice of delegations of authority.

SUMMARY: This document provides the public notice of the delegations of authority for activities related to loans guaranteed under the Paycheck Protection Program (PPP) by the Administrator of the Small Business Administration (SBA) to the Associate Administrator for the Office of Capital Access (AA/OCA) and the redelegation of certain authority related to PPP loan activities to the Director of the Office of Financial Program Operations (OFPO) in the OCA, certain employees of OFPO, and an OCA Committee. In addition, this document provides the public notice of the delegations of authority for certain activities related to Coronavirus Disease 2019 (COVID–19) Economic Injury Disaster Loans (EIDLs) and EIDL Advances by the Administrator to the AA/OCA.

SUPPLEMENTARY INFORMATION: This document provides the public notice of the Administrator's delegations of authority with respect to the temporary 7(a) loan program titled the ''Paycheck Protection Program'' (PPP) under sections 7(a)(36), 7(a)(37), and 7A of the Small Business Act (15 U.S.C. 636(a)(36) and (37); 15 U.S.C. 636m) to the AA/OCA. Specifically, the delegation of authority related to SBA's review of PPP loans and final SBA loan review decisions, as well as the servicing, liquidation, and guaranty purchase of PPP loans. The delegation of authority related to guaranty purchases of PPP loans is consistent with the delegation of authority published at 68 FR 51048 (August 25, 2003) for guaranty purchases of other 7(a) loans. This document also provides that certain authority for PPP loan activities delegated to the AA/OCA is redelegated to the OFPO Director, certain OFPO employees, and to an OCA Committee. Finally, notwithstanding the Delegation of Authority No. 12–D, Revision 3 (58 FR 57891), which sets forth the authority delegated by the Administrator to the Assistant Administrator for Disaster Assistance for the purpose of administering SBA's Disaster Assistance Programs, this document provides the public notice of the Administrator's delegation of authority to the AA/OCA for certain activities related to SBA's Coronavirus Disease 2019 (COVID–19) Economic Injury Disaster Loans (COVID EIDLs) and EIDL Advances, including Targeted EIDL Advances and Supplemental Targeted Advances. All other delegations of authority for the purpose of administering SBA's Disaster Assistance Programs, remain as set forth in Delegation of Authority No. 12–D, Revision 3.

Delegation of Authority No. 12–H reads as follows:

Delegation of Authority No. 12–H.

I. The Administrator of the SBA, Isabella Casillas Guzman, pursuant to the authority vested in her by the Small Business Act, 15 U.S.C. 631, as amended, hereby delegates the following authorities related to loan activities of the Paycheck Protection Program (PPP) under sections 7(a)(36), 7(a)(37) and 7A of the Small Business Act, 15 U.S.C. 636(a)(36) and (37) and 15 U.S.C. 636m:

A. To the Associate Administrator for the Office of Capital Access (AA/OCA):

1. Loan Reviews and Decisions:

a. To take any and all action(s) in connection with SBA's review of PPP loans in accordance with the implementing guidance for the PPP issued by SBA and the Department of the Treasury, including but not limited to interim final rules, final rules, frequently asked questions, SBA notices, and official SBA forms, including instructions for those forms (collectively the ''PPP requirements'').

b. To make all final SBA loan review decisions, including but not limited to, whether the borrower:

i. Was ineligible for the PPP loan;

ii. Was ineligible for the PPP loan amount received or used the PPP loan proceeds for unauthorized purposes;

iii. Is ineligible for PPP loan forgiveness in the amount determined by the lender in its full or partial approval decision issued to SBA; and/or

iv. Is ineligible for PPP loan forgiveness in any amount when the lender has issued a full denial decision to SBA.

2. Servicing, Liquidation, Denial of Liability on a Guaranty on a PPP Loan, and Approve Initiation of Lawsuit to Recover Funds on a PPP Loan:

a. To determine whether the PPP lender complied with all SBA Loan Program Requirements related to servicing, liquidation, and litigation of its PPP loans, including but not limited to borrowers involved in bankruptcy.

b. Consistent with the delegation of authority published at 68 FR 51048 (August 25, 2003), to take any and all actions involved in denial of liability on guaranty purchase requests submitted on PPP loans and to approve the initiation of a lawsuit to recover funds on a PPP loan from a PPP lender, including but not limited to recovery of the processing fee paid to a lender that is found guilty of an act of fraud in connection with a PPP loan.

c. To approve the initiation of a lawsuit to recover funds on a PPP loan from a borrower, including but not limited to recovery of funds from the borrower's shareholder(s), member(s), or partner(s) if the shareholder, member, or partner knowingly used the funds for unauthorized purposes.

3. To amend, suspend, or revoke authority redelegated to any position listed below.

B. The authority delegated to the AA/OCA is redelegated to the Director, Office of Financial Program Operations, as follows:

1. Loan Reviews:

a. To determine and develop policy and procedures necessary for SBA staff in headquarters and relevant SBA loan centers, as well as applicable contractor staff, to conduct loan review activities related to PPP loans.

b. To oversee the performance of loan reviews of PPP loans by SBA staff in headquarters and relevant SBA loan centers, as well as applicable contractor staff.

2. Servicing, Liquidation, and Guaranty Purchase of PPP Loans:

a. To determine and develop policy and procedures necessary for SBA staff in headquarters and relevant SBA loan centers, as well as applicable contractor staff, to conduct servicing, liquidation,

and guaranty purchase activities related to PPP loans.

b. To oversee the performance of servicing, liquidation, and guaranty purchase activities of PPP loans by SBA staff in headquarters and relevant SBA loan centers, as well as applicable contractor staff.

C. The authority delegated to the AA/OCA is redelegated to the specific positions designated herein as follows:

1. Loan Specialists, SBA loan centers:

a. Reviewing Loan Specialist:

i. To review all documentation submitted by the borrower and lender in connection with a PPP loan and to request additional information from the borrower or lender as necessary to complete the SBA loan review in accordance with PPP requirements.

ii. To make a recommendation to the Approving Loan Specialist as to whether the borrower was eligible for the PPP loan; was eligible for the PPP loan amount received, or used the PPP loan proceeds for authorized purposes; and/or is eligible for PPP loan forgiveness and in what amount.

b. Approving Loan Specialist:

i. To review and concur with the Reviewing Loan Specialist's recommendation in paragraph 1.a.ii. above and make the final SBA loan review decision, except in the circumstances described in subparagraph b.ii. below.

ii. To escalate to the Higher Authority Review Team all recommendations when:

(1) The Approving Loan Specialist and Reviewing Loan Specialist agree that loan forgiveness will be denied in whole or in part; and

(2) The Approving Loan Specialist does not concur with the Reviewing Loan Specialist's recommendation, including when the Approving Loan Specialist and Reviewing Loan Specialist disagree on the amount of loan forgiveness the borrower is entitled to receive.

2. Higher Authority Review Team:

a. This team will consist of more experienced employees from the SBA loan centers.

b. This team will have the authority to perform Higher Authority Reviews (HAR). This team will also have the authority to make the final SBA loan review decision on all loan reviews escalated to the team unless the HAR team escalates a loan review to the Office of Capital Access Committee in accordance with paragraph 2.c. below. The Higher Authority Review will consist of separate reviews by a Reviewing Loan Specialist and an Approving Loan Specialist.

c. The HAR team, at their discretion, will have the authority, on a case-by-case basis, to escalate a loan review to the Office of Capital Access Committee for the final SBA loan review decision.

3. To the Office of Capital Access (OCA) Committee:

a. This committee will consist of the Director, Office of Financial Assistance (or designee); the Director, Office of Credit Risk Management (or designee); and the career Deputy Associate Administrator (DAA), Office of Capital Access (or designee).

b. The OCA Committee will have the authority to review and make a final SBA loan review decision, upon a majority vote of its members, on all loan reviews that are escalated after the Higher Authority Review.

II. Except for actions involved in the denial of liability on a guaranty purchase request submitted on a PPP loan and the decision to approve the initiation of a lawsuit to recover funds on a PPP loan from a PPP lender or borrower, the authorities delegated herein to the AA/OCA may be re-delegated. All other authority delegated herein to anyone other than the AA/OCA may not be re-delegated, except by the AA/OCA.

III. The Administrator of the SBA, Isabella Casillas Guzman, pursuant to the authority vested in her by the Small Business Act, 15 U.S.C. 631, as amended, hereby delegates the following authorities related to SBA's Coronavirus Disease 2019 (COVID–19) Economic Injury Disaster Loans (COVID EIDLs) under section 7(b)(2) of the Small Business Act (15 U.S.C. 636(b)(2)) and section 1110 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136), as amended, and EIDL Advances, including Targeted EIDL Advances and Supplemental Targeted Advances under section 1110 of the CARES Act, as amended, section 331 of the Economic Aid to Hard-Hit Small Businesses, Nonprofits, and Venues Act (Pub. L. 116–260), and section 5002 of the American Rescue Plan Act of 2021 (Pub. L. 117–2):

A. To the Associate Administrator for the Office of Capital Access (AA/OCA):

1. To establish and revise policies regarding the eligibility for and processing of COVID EIDL loans and EIDL Advances.

2. To procure supplies or services in support of the COVID EIDL loan and EIDL Advance programs, and in accordance with 41 U.S.C. 4701(a) and (b), as amended, the Federal Acquisition Regulations, SBA regulations, and applicable procurement policies.

3. This authority may not be redelegated.

IV. The authorities delegated to any position indicated herein may be exercised by any SBA employee officially designated as Acting in that position.

V. The authorities delegated herein can only be revoked or amended by the Administrator and in writing.

Authority: 15 U.S.C. 631; 15 U.S.C. 636(a)(36); 15 U.S.C. 636(a)(37); 15 U.S.C. 636(b)(2); 15 U.S.C. 636m; Sec. 1110, Pub. L. 116–136, 134 Stat. 281; Sec. 331, Pub. L. 116–260; and Sec. 5002, Pub. L. 117–2, 135 Stat. 4.

Isabella Casillas Guzman,

Administrator.

[FR Doc. 2021–24908 Filed 11–15–21; 8:45 am]

BILLING CODE 8026–03–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Product Exclusion Extensions: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice.

SUMMARY: In prior notices, the U.S. Trade Representative modified the action in the Section 301 investigation of China's acts, policies, and practices related to technology transfer, intellectual property, and innovation by excluding from additional duties certain medical-care products needed to address the COVID–19 pandemic. The 99 exclusions for medical care products to address COVID–19 were published on December 29, 2020, and are scheduled to expire on November 14, 2021. On August 27, 2021, USTR requested comments on whether to extend the COVID exclusions. This notice announces the U.S. Trade Representative's determination to provide a 16-day transition period for all COVID exclusions (through November 30, 2021), and to extend 81 of the COVID exclusions for an additional 6 months.

DATES: To provide a transition period, this notice extends the 99 exclusions scheduled to expire on November 14, 2021, through November 30, 2021. Those exclusions receiving further extensions will expire six months after November 30, 20201, on May 31, 2022. U.S. Customs and Border Protection will issue instructions on entry guidance and implementation.

FOR FURTHER INFORMATION CONTACT: For general questions about this notice, contact Associate General Counsel Philip Butler or Assistant General Counsel Rachel Komito at (202) 395–5725. For specific questions on customs classification or implementation of the product exclusions, contact *traderemedy@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

In the course of this investigation the U.S. Trade Representative imposed additional duties on products of China in four tranches. *See* 83 FR 28719 (June 20, 2018); 83 FR 40823 (August 16, 2018); 83 FR 47974 (September 21, 2018), as modified by 83 FR 49153 (September 28, 2018); and 84 FR 43304 (August 20, 2019), as modified by 84 FR 69447 (December 18, 2019) and 85 FR 3741 (January 22, 2020).

For each tranche, the U.S. Trade Representative established a process by which U.S. stakeholders could request the exclusion of particular products subject to the action. The U.S. Trade Representative later established a process by which U.S. stakeholders could request the extension of particular exclusions. Additionally, on March 25, 2020, the U.S. Trade Representative requested public comments on possible further modifications to remove Section 301 duties from medical-care products to address the COVID–19 pandemic. 85 FR 16987.

On December 29, 2020, USTR announced the extension of 80 product exclusions on medical-care and/or COVID response products; further modifications in the form of 19 product exclusions to remove Section 301 duties from additional medical-care and/or COVID response products; and that USTR might consider further extensions and/or modifications as appropriate. *See* 85 FR 85831 (the December 29 notice). On March 10, 2021, USTR announced the extension of these 99 exclusions until September 30, 2021, and that USTR might consider further extensions and/or modifications as appropriate. 86 FR 13785. On August 27, 2021, USTR published a notice requesting public comments on whether any of these exclusions should be further extended for up to six months. 86 FR 48280 (the August 27 notice). The August 27 notice stated that USTR would evaluate each exclusion on a case-by-case basis and the evaluation would examine whether the exclusion remains appropriate in light of recent developments including the spread of the Delta variant in the United States and increased domestic production of certain products, and taking account of the overall impact of these exclusions on the goal of obtaining the elimination of China's acts, policies, and practices covered in this Section 301 investigation.

On September 29, 2021, USTR announced the interim extension of these 99 exclusions through November 14, 2021, in order to provide time to review public comments submitted in response to the August 27 notice. 86 FR 54011.

B. Determination To Extend Certain Exclusions

Based on evaluation of the factors set out in in the August 27 notice, and pursuant to sections 301(b), 301(c), and 307(a) of the Trade Act of 1974, as amended, the U.S. Trade Representative has determined to extend certain product exclusions described in the December 29 notice for six months past the expiry of the remaining exclusions (until May 31, 2022), as set out in the annexes to this notice. The U.S. Trade Representative's determination considers public comments submitted in response to the August 27 notice, and the advice of advisory committees, the interagency Section 301 Committee, and the White House COVID–19 Response Team.

To provide a transition period for the expiring exclusions, the U.S. Trade Representative has determined to extend all 99 product exclusions described in the December 29 notice through November 30, 2021.

The exclusion extensions are available for any product that meets the description in the product exclusion. Further, the scope of each exclusion and modification is governed by the scope of the ten-digit Harmonized Tariff Schedule of the United States (HTSUS) subheadings and product descriptions in the annexes to this notice. U.S. Customs and Border Protection will issue instructions on entry guidance and implementation.

The U.S. Trade Representative may continue to consider further extensions and/or additional modifications as appropriate.

Greta Peisch,

General Counsel, Office of the United States Trade Representative.

BILLING CODE 3290–F2–P

Annex for COVID Extensions

Annex A

Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on November 15, 2021, and before 11:59 p.m. eastern daylight time on November 30, 2021, each of the article descriptions of headings 9903.88.62, 9903.88.63, 9903.88.64 and 9903.88.65 of the Harmonized Tariff Schedule of the United States are modified by deleting "November 14, 2021," and by inserting "November 30, 2021," in lieu thereof.

Annex B

A. Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on December 1, 2021 and before 11:59 p.m. eastern daylight time on May 31, 2022, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified:

1. by inserting the following new heading 9903.88.66 in numerical sequence, with the material in the new heading inserted in the columns of the HTSUS labeled "Heading/Subheading", "Article Description", and "Rates of Duty 1-General", respectively:

Heading/ Subheading	Article Description	Rates of Duty		
		1		2
		General	Special	
"9903.88.66	Effective with respect to entries on or after December 1, 2021, and before June 1, 2022, articles the product of China, as provided for in U.S. note 20(sss) to this subchapter, each covered by an exclusion granted by the U.S. Trade Representative	The duty provided in the applicable subheading"		

2. by inserting the following new U.S. note 20(sss) to subchapter III of chapter 99 in numerical sequence:

"(sss) (i) The U.S. Trade Representative determined to establish a process by which particular products classified in heading 9903.88.01 and provided for in U.S. notes 20(a) and 20(b) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.01. See 83 Fed. Reg. 40823 (August 16, 2018) and 83 Fed. Reg. 47326 (September 18, 2018). Pursuant to the product exclusion process, the U.S. Trade Representative has determined that, as provided in heading 9903.88.66, the additional duties provided for in heading 9903.88.01 shall not apply to the following particular products, which are provided for in the enumerated statistical reporting numbers:

(1) Disposable plastic filters of a kind suitable for filtering and dehumidifying a patient's breath in a medical device such as a gas analyzer (described in statistical reporting number 8421.39.8090)

(2) S-band and X-band linear accelerators designed for use in radiation surgery or radiation therapy equipment (described in statistical reporting number 8543.10.0000)
(3) Disposable electrocardiograph (ECG) electrodes (described in statistical reporting number 9018.11.9000)
(4) Ultrasonic scanning apparatus, each having dimensions not exceeding 122 cm by 77 cm by 127 cm, whether or not presented with transducer (described in statistical reporting number 9018.12.0000)
(5) Blood pressure monitors suitable for use by medical professionals (described in statistical reporting number 9018.19.9530)
(6) Digital peak flow meters suitable for use by medical professionals (described in statistical reporting number 9018.19.9550)
(7) Fingertip pulse oximeters suitable for use by medical professionals (described in statistical reporting number 9018.19.9550)
(8) Bismuth germanate crystals with set dimensional and surface finish requirements and used as a detection element in Positron Emission Tomography (PET) detectors (described in statistical reporting number 9018.19.9560)
(9) Magnetic resonance imaging ("MRI") patient enclosure devices, each incorporating radio frequency and gradient coils (described in statistical reporting number 9018.19.9560)
(10) Parts and accessories of capnography monitors (described in statistical reporting number 9018.19.9560)
(11) Disposable surface electrodes for Intra-operative neuromonitoring ("IONM") systems, each composed of a surface electrode pad, an insulated wire, and a standard DIN 42802 connector (described in statistical reporting number 9018.19.9560)
(12) Otoscopes (described in statistical reporting number 9018.90.2000)
(13) Anesthesia masks (described in statistical reporting number 9018.90.3000)
(14) Anesthetic instruments and appliances suitable for use in medical or surgical sciences, and parts and accessories of the foregoing (described in statistical reporting number 9018.90.3000)
(15) Electrosurgical cautery pencils with electrical connectors (described in statistical reporting number 9018.90.6000)
(16) Printed circuit board assemblies designed for use in displaying operational performance of medical infusion equipment (described in statistical reporting number 9018.90.7580)
(17) Combined positron emission tomography/computed tomography (PET/CT) scanners which utilize multiple PET gantries (frames) on a common base (described in statistical reporting number 9022.12.0000)
(18) X-ray tables (described in statistical reporting number 9022.90.2500)
(19) X-ray tube housings and parts thereof (described in statistical reporting number 9022.90.4000)
(20) Multi-leaf collimators of radiotherapy systems based on the use of X-ray (described in statistical reporting number 9022.90.6000)
(21) Parts and accessories, of metal, for mobile X-ray apparatus (described in statistical reporting number 9022.90.6000)
(22) Vertical stands specially designed to support, contain or adjust the movement of X-ray digital detectors, or the X-ray tube and collimator in complete X-ray diagnostic systems (described in statistical reporting number 9022.90.6000)

(23) Thermoplastic masks of polycaprolactone for the use of immobilizing patients, during the use of alpha, beta or gamma radiations, for radiography or radiotherapy (described in statistical reporting number 9022.90.9500)

(24) Inoculator sets of plastics, each consisting of a plate with multiple wells, a display tray, and a lid; when assembled, the set measuring 105 mm or more but not exceeding 108 mm in width, 138 mm or more but not exceeding 140 mm in depth, and 6.5 mm or less in thickness (described in statistical reporting number 9027.90.5650)

(ii) The U.S. Trade Representative determined to establish a process by which particular products classified in heading 9903.88.02 and provided for in U.S. notes 20(c) and 20(d) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.02. See 83 Fed. Reg. 40823 (August 16, 2018) and 83 Fed. Reg. 47326 (September 18, 2018). Pursuant to the product exclusion process, the U.S. Trade Representative has determined that, as provided in heading 9903.88.66, the additional duties provided for in heading 9903.88.02 shall not apply to the following particular products, which are provided for in the enumerated statistical reporting numbers:

(1) 9025.19.8010
(2) 9025.19.8020
(3) 9025.19.8060
(4) 9025.19.8085
(5) Molded acrylonitrile-butadiene-styrene (ABS) tubes, of a kind used to effect the sterile transfer of fluid from a bag or vial to another container, each tube measuring 7.5 cm or more but not exceeding 23 cm in length, with an inner diameter of less than 0.65 cm and an outer diameter of less than 9 cm, one end having been angle-cut to form a spike, and having an integrated flange, less than 3 cm in diameter (splash guard) near the spike end and removable polyethylene caps on each end, put up in sterile packing (described in statistical reporting number 3917.29.0090)
(6) Rectangular sheets of high-density or low-density polyethylene, 111.75 cm to 215.9 cm in width, and 152.4 cm to 304.8 cm in length, with a sticker attached to mark the center of each sheet, of a kind used in hospital or surgery center operating rooms (described in statistical reporting number 3920.10.0000)
(7) Sheets and strips consisting of both cross-linked polyethylene and ethylene vinyl acetate, of a width greater than 1 m but not greater than 1.5 m, and a length greater than 1.75 m but not greater than 2.6 m (described in statistical reporting number 3921.19.0000)
(8) Polyethylene sheet and film laminated with spunbond-spunbond-spunbond nonwoven polypropylene fabric, measuring 1.12 m or more but not over 1.52 m in width and 1.93 m or more but not over 2.29 m in length, and weighing 55 g/m^2 or more but not exceeding 88 g/m^2 (described in statistical reporting number 3921.90.1500)
(9) Dispensers of hand-cleaning or hand-sanitizing solutions, whether employing a manual pump or a proximity-detecting battery-operated pump, each article weighing not more than 3 kg (described in statistical reporting number 8424.89.9000)

(iii) The U.S. Trade Representative determined to establish a process by which particular products classified in heading 9903.88.03 and provided for in U.S. notes 20(e) and 20(f) to this subchapter could be excluded from the additional duties imposed by heading

9903.88.03, and by which particular products classified in heading 9903.88.04 and provided for in U.S. note 20(g) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.04. See 83 Fed. Reg. 47974 (September 21, 2018) and 84 Fed. Reg. 29576 (June 24, 2019). Pursuant to the product exclusion process, the U.S. Trade Representative has determined that, as provided in heading 9903.88.66, the additional duties provided for in heading 9903.88.03 or in heading 9903.88.04 shall not apply to the following particular products, which are provided for in the enumerated statistical reporting numbers:

(1) 3808.94.1000
(2) 3808.94.5010
(3) 3923.21.0095
(4) 3926.20.9050
(5) 4819.50.4060
(6) 5603.12.0090
(7) 5603.14.9090
(8) 5603.92.0090
(9) 5603.93.0090
(10) 6505.00.8015
(11) 8424.90.9080
(12) Sodium metal (CAS No. 7440-23-5), in bulk solid form (described in statistical reporting number 2805.11.0000)
(13) Disposable cloths of nonwoven textile materials impregnated, coated or covered with organic surface-active preparations for washing the skin, put up for retail sale (described in statistical reporting number 3401.30.5000)
(14) Mixtures containing 2-(dimethylamino)ethanol (CAS No. 108-01-0) (described in statistical reporting number 3824.99.9297)
(15) Silicon monoxide (SiO) (CAS No. 10097-28-6) in powder form (described in statistical reporting number 3824.99.9297)
(16) Flexible gas sampling tubes, pipes and hoses, of polyvinyl chloride, with lock connectors at each end (described in statistical reporting number 3917.33.0000)
(17) Flexible oxygen tubes, pipes and hoses presented with integrated molded connectors, of polyvinyl chloride (described in statistical reporting number 3917.33.0000)
(18) Container units of plastics, each comprising a tub and lid therefore, configured or fitted for the conveyance, packing, or dispensing of wet wipes (described in statistical reporting number 3923.10.9000)
(19) Sacks and bags of polymers of ethylene, reclosable, qualifying as Class 1 medical devices by the U.S. Food and Drug Administration under product code NNI (described in statistical reporting number 3923.21.0030)
(20) Injection molded polypropylene plastic caps or lids each weighing not over 24 grams designed for dispensing wet wipes (described in statistical reporting number 3923.50.0000)
(21) Hand pumps (other than for fuel or lubricants, not fitted or designed to be fitted with a metering device), each used to dispense a metered quantity of liquid soap or sanitizer (described in statistical reporting number 8413.20.0000)
(22) Hand pumps for liquids (other than those of subheading 8413.11 or 8413.19) of acrylonitrile butadiene styrene (ABS) plastics (described in statistical reporting number 8413.20.0000)
(23) Indicator panels incorporating LEDs, designed for use in medical infusion equipment (described in statistical reporting number 8531.20.0040)

(24) Data input devices each with display capabilities of a kind used for magnetic resonance imaging ("MRI") equipment, computed tomography ("CT") equipment, intraoperative X-ray ("IXR") equipment or patient monitors (described in statistical reporting number 8537.10.9170)
(25) Compound binocular optical microscopes (other than stereoscopic microscopes and microscopes for photomicrography, cinemicrography or microprojection), each with magnification of 40X or more but not exceeding 1,000X, weighing not more than 3 kg (described in statistical reporting number 9011.80.0000)
(26) Compound optical microscopes (other than stereoscopic microscopes and microscopes for photomicrography, cinemicrography or microprojection), each with magnification of 40X or more but not exceeding 400X, weighing not more than 15 kg (described in statistical reporting number 9011.80.0000)

"(iv) The U.S. Trade Representative determined to establish a process by which particular products classified in heading 9903.88.15 and provided for in U.S. notes 20(r) and (s) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.15. See 84 Fed. Reg. 43304 (August 20, 2019), 84 Fed. Reg. 45821 (August 30, 2019), 84 Fed. Reg. 57144 (October 24, 2019) and 85 Fed. Reg. 3741 (January 22, 2020). Pursuant to the product exclusion process, the U.S. Trade Representative has determined that, as provided in heading 9903.88.66, the additional duties provided for in heading 9903.88.15 shall not apply to the following particular products, which are provided for in the following enumerated statistical reporting numbers:

(1) 3401.19.0000
(2) 3926.90.9910
(3) 4818.90.0000 prior to July 1, 2020; 4818.90.0020 or 4818.90.0080 effective July 1, 2020
(4) 5210.11.4040
(5) 5210.11.6020
(6) 5504.10.0000
(7) 6210.10.5010
(8) 6210.10.5090
(9) 6307.90.7200
(10) Face shields of transparent plastics, whether or not assembled (described in statistical reporting number 3926.90.9950)
(11) Bowls of molded plastics, with clips for retaining guide wires during surgical procedures (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)
(12) Coverings, of plastics, designed to fit over wound sites or casts thereby forming a protective seal for keeping the covered area dry and debris free while showering or bathing (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)
(13) Disposable graduated medicine dispensing cups of plastics (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)
(14) Single-use sterile drapes and covers of plastics, of a kind used to protect the sterile field in surgical operating rooms (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)

(15) Sterile decanters of polystyrene plastics, each of a kind used to transfer aseptic fluids or medication to and from sterile bags, vials or glass containers (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)
(16) Cold packs consisting of a single-use, instant, endothermic chemical reaction cold pack combined with a textile exterior lining (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
(17) Hot packs of textile material, single-use (exothermic chemical reaction) (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
(18) Laparotomy sponges of cotton (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
(19) Single-use blood pressure cuff sleeves of textile materials (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
(20) Single-use stethoscope covers (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
(21) Woven gauze sponges of cotton in square or rectangular sizes (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
(22) Protective Articles (described in statistical reporting number 9004.90.0000 prior to January 1, 2021; described in statistical reporting number 9004.90.0010 or 9004.90.0090 effective January 1, 2021)".

3. by amending the last sentence of the first paragraph of U.S. note 20(a) to subchapter III of chapter 99 by:

   a. by deleting "or (13)" and by inserting "(13)" in lieu thereof; and

   b. by inserting "; or (14) heading 9903.88.66 and U.S. note 20(sss)(i) to subchapter III of chapter 99" after the phrase "U.S. note 20(ooo) to subchapter III of chapter 99", where it appears at the end of the sentence.

4. by amending U.S. note 20(b) to subchapter III of chapter 99 by:

   a. by deleting "or (13)" and by inserting "(13)" in lieu thereof; and

   b. by inserting "; or (14) heading 9903.88.66 and U.S. note 20(sss)(i) to subchapter III of chapter 99" after the phrase "U.S. note 20(ooo) to subchapter III of chapter 99", where it appears at the end of the sentence.

5. by amending the last sentence of the first paragraph of U.S. note 20(c) to subchapter III of chapter 99 by:

   a. by deleting "or (7)" and by inserting "(7)" in lieu thereof; and

b. by inserting "; or (8) heading 9903.88.66 and U.S. note 20(sss)(ii) to subchapter III of chapter 99" after the phrase "U.S. note 20(ppp) to subchapter III of chapter 99", where it appears at the end of the sentence.

6. by amending U.S. note 20(d) to subchapter III of chapter 99 by:

   a. by deleting "or (7)" and by inserting "(7)" in lieu thereof; and

   b. by inserting "; or (8) heading 9903.88.66 and U.S. note 20(sss)(ii) to subchapter III of chapter 99" after the phrase "U.S. note 20(ppp) to subchapter III of chapter 99", where it appears at the end of the sentence.

7. by amending the last sentence of the first paragraph of U.S. note 20(e) to subchapter III of chapter 99 by:

   a. by deleting "or (16)" and by inserting "(16)" in lieu thereof; and

   b. by inserting "; or (17) heading 9903.88.66 and U.S. note 20(sss)(iii) to subchapter III of chapter 99" after the phrase "U.S. note 20(qqq) to subchapter III of chapter 99", where it appears at the end of the sentence.

8. by amending U.S. note 20(f) to subchapter III of chapter 99 by:

   a. by deleting "or (16)" and by inserting "(16)" in lieu thereof; and

   b. by inserting "; or (17) heading 9903.88.66 and U.S. note 20(sss)(iii) to subchapter III of chapter 99" after the phrase "U.S. note 20(qqq) to subchapter III of chapter 99", where it appears at the end of the sentence.

9. by amending the last sentence of the first paragraph of U.S. note 20(r) to subchapter III of chapter 99:

   a. by deleting "or (10)" and by inserting "(10)" in lieu thereof; and

   b. by inserting ", or (11) heading 9903.88.66 and U.S. note 20(sss)(iv) to subchapter III of chapter 99" after "U.S. note 20(rrr) to subchapter III of chapter 99".

10. by amending the article description of heading 9903.88.01:

    a. by deleting "9903.88.60 or";

    b. by inserting in lieu thereof "9903.88.60,"; and

    c. by inserting "or 9903.88.66," after "9903.88.62,".

11. by amending the article description of heading 9903.88.02:

    a. by deleting "9903.88.61 or";

    b. by inserting in lieu thereof "9903.88.61,"; and

c. by inserting "or 9903.88.66," after "9903.88.63,".

12. by amending the article description of heading 9903.88.03:

a. by deleting "9903.88.56 or";

b. by inserting in lieu thereof "9903.88.56,"; and

c. by inserting "or 9903.88.66," after "9903.88.64,".

13. by amending the article description of heading 9903.88.04:

a. by deleting "9903.88.56 or";

b. by inserting in lieu thereof "9903.88.56," ; and

c. by inserting "or 9903.88.66" after "9903.88.64".

14. by amending the article description of heading 9903.88.15:

a. by deleting "9903.88.57 or" and by inserting "9903.88.57," in lieu thereof; and

b. by inserting "or 9903.88.66," after "9903.88.65,".

[FR Doc. 2021–24918 Filed 11–15–21; 8:45 am]
BILLING CODE 3290–F2–C

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2021–0004]

Petition for Exemption; Summary of Petition Received; Skyways Air Transportation, Inc.

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 6, 2021.

ADDRESSES: Send comments identified by docket number FAA–2020–1190 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *https://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 683–7788, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Caitlin Locke,

Acting Executive Deputy Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2020–1190.

Petitioner: Skyways Air Transportation, Inc.

Section(s) of 14 CFR Affected: §§ 61.113(a) & (b); 91.7(a); 91.109; 91.119(c); 91.121(a)(1); 91.405(a); 91.407(a)(1); 91.409(a)(1) & (2); 91.417(a) & (b).

Description of Relief Sought: Skyways Air Transportation, Inc. (Skyways) seeks relief to operate the Skyways V2.50

vertical takeoff and landing unmanned aircraft system, weighing over 55 pounds (lbs.) but no more than 155 lbs., to conduct market research and demonstration flights. Operations will be conducted within visual line-of-sight during the daytime, below 400 feet above ground level, in remote sparsely populated areas of Class G airspace overland and overwater.

[FR Doc. 2021–24996 Filed 11–15–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

[Docket No. TTB–2021–0003]

Proposed Information Collections; Comment Request (No. 84)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau (TTB), Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of our continuing effort to reduce paperwork and respondent burden, and as required by the Paperwork Reduction Act of 1995, we invite comments on the proposed or continuing information collections listed below in this notice.

DATES: We must receive your written comments on or before January 18, 2022.

ADDRESSES: You may send comments on the information collections described in this document using one of the two methods described below—

- *Internet:* To submit comments electronically, use the comment form for this document posted on the ''*Regulations.gov*'' e-rulemaking website at *https://www.regulations.gov* within Docket No. TTB–2021–0003.
- *Mail:* Send comments to the Paperwork Reduction Act Officer, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005.

Please submit separate comments for each specific information collection described in this document. You must reference the information collection's title, form or recordkeeping requirement number (if any), and OMB control number in your comment.

You may view copies of this document, the relevant TTB forms, and any comments received at *https://www.regulations.gov* within Docket No. TTB–2021–0003. TTB has posted a link to that docket on its website at *https://www.ttb.gov/rrd/information-collection-notices.* You also may obtain paper copies of this document, the listed forms, and any comments received by contacting TTB's Paperwork Reduction Act Officer at the addresses or telephone number shown below.

FOR FURTHER INFORMATION CONTACT: Michael Hoover, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; 202–453–1039, ext. 135; or *informationcollections@ttb.gov* (please do not submit comments to this email address).

SUPPLEMENTARY INFORMATION:

Request for Comments

The Department of the Treasury and its Alcohol and Tobacco Tax and Trade Bureau (TTB), as part of a continuing effort to reduce paperwork and respondent burden, invite the general public and other Federal agencies to comment on the proposed or continuing information collections described below, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Comments submitted in response to this document will be included or summarized in our request for Office of Management and Budget (OMB) approval of the relevant information collection. All comments are part of the public record and subject to disclosure. Please do not include any confidential or inappropriate material in your comments.

We invite comments on: (a) Whether an information collection is necessary for the proper performance of the agency's functions, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the information collection's burden; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the information collection's burden on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide the requested information.

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 has a valid OMB control number.

Information Collections Open for Comment

Currently, we are seeking comments on the following forms, letterhead applications or notices, recordkeeping requirements, questionnaires, or surveys:

OMB Control No. 1513–0013

Title: Change in Bond (Change of Surety).

TTB Form Number: TTB F 5000.18.

Abstract: The Internal Revenue Code (IRC), at 26 U.S.C. 5114, 5173, 5272, 5354, 5401, and 5711, requires certain alcohol and tobacco industry proprietors to post a bond as the Secretary of the Treasury (the Secretary) requires by regulation. The required bond ensures payment of alcohol and tobacco excise taxes by a surety if a proprietor defaults on those taxes. Changes in the terms of bonds are effectuated on form TTB F 5000.18, Change in Bond (Consent of Surety). Once executed by the proprietor and an approved surety company, the proprietor files the form with TTB, which retains it as long as the revised bond agreement remains in force. This collection is necessary to ensure the tax provisions of the IRC are appropriately applied.

Current Actions: There are no program or adjustments changes associated with this information collection, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden

- *Number of Respondents:* 120.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 120.
- *Average per-Response Burden:* 1 hour.
- *Total Burden:* 120 hours.

OMB Control No. 1513–0020

Title: Application for and Certification/Exemption of Label/Bottle Approval.

TTB Form Number: TTB F 5100.31.

Abstract: The Federal Alcohol Administration Act (FAA Act) at 27 U.S.C. 205(e) requires that alcohol beverages sold or introduced into interstate or foreign commerce be labeled in conformity with regulations issued by the Secretary. Under the FAA Act, such regulations are to prevent deception of the consumer, provide the consumer with ''adequate information'' as to the identity and quality of the product, and prohibit false or misleading statements, among other things. Further, under the FAA Act, prior to an alcohol beverage product's introduction into interstate or foreign commerce, the producer, bottler, or

importer of the product must apply for and receive TTB approval of the product's label. For wines and distilled spirits, such respondents also may apply for exemption from label approval for products not sold or entered into interstate or foreign commerce. For distilled spirits, the TTB regulations also require approval of distinctive liquor bottles. Respondents use form TTB F 5100.31 or its electronic equivalent, COLAs Online, to request and obtain such approvals. If approved by TTB, the form also serves as a certificate of label approval (COLA), a certificate of exemption from label approval, or distinctive liquor bottle approval. This collection of information and its related form implement these statutory and regulatory provisions.

Current Actions: As for program changes, TTB is adding to its instructions to provide four new ''allowable revisions'' to alcohol beverage labels described on TTB F 5100.31 and COLAs Online. TTB is also expanding two allowable revision that were already provided. ''Allowable revisions'' are revisions that can be made to a label without requiring the submission of a new COLA application; see TTB Industry Circular 2021–1, at *https://ttb.gov/industry-circulars,* for details. These changes allow respondents more flexibility in changing labels without prior TTB approval and will reduce the overall number of COLA applications required to be submitted to TTB. As for adjustments, due to changes in agency estimates resulting from increases in the number of COLA applications TTB annually receives, TTB is increasing the number of annual respondents, responses, and burden hours associated with this collection.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden

- *Number of Respondents:* 12,500.
- *Average Responses per Respondent:* 16.4.
- *Number of Responses:* 205,000.
- *Average per-Response Burden:* 31 minutes.
- *Total Burden:* 105,917 hours.

OMB Control No. 1513–0026

Title: Claims for Drawback of Tax on Tobacco Products, Cigarette Papers, and Cigarette Tubes Exported from the United States.

TTB Form Numbers: TTB F 5200.17 and TTB F 5620.7.

Abstract: The IRC at 26 U.S.C. 5706 provides for the drawback (refund) of Federal excise taxes paid on tobacco products, and on cigarette papers and tubes, when such articles are subsequently exported in accordance with the bond and regulatory requirements prescribed by the Secretary. Under that authority, the TTB regulations in 27 CFR part 44 provide for drawback of excise taxes paid on such products shipped to a foreign country, Puerto Rico, the Virgin Islands, or a possession of the United States when the person who paid the tax files the prescribed claim and bond. The regulations require that respondents file such claims and certain supporting documentation using form TTB F 5620.7, while the required bond is filed using form TTB F 5200.17. In addition, respondents may file letterhead applications for relief from certain regulatory requirements regarding filing of supporting documentation showing export or loss. This collection ensures drawback is provided consistent with the statutory provisions.

Current Actions: There are no program changes or adjustments associated with this information collection at this time, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

Estimated Annual Burden

- *Number of Respondents:* 13.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 13.
- *Average per-Response Burden:* 1.385 hours.
- *Total Burden:* 18 hours.

OMB Control No. 1513–0027

Title: Removals of Tobacco Products and Cigarette Papers and Tubes without Payment of Tax.

TTB Form Number: TTB F 5200.14.

Abstract: The IRC at 26 U.S.C. 5704(b) provides that a manufacturer or export warehouse proprietor, in accordance with regulations prescribed by the Secretary, may remove tobacco products and cigarette papers and tubes, without payment of tax, for export or consumption beyond the jurisdiction of the internal revenue laws of the United States. That IRC section also provides that such persons may transfer such articles, without payment of tax, to the bonded premises of another such entity. In addition, the IRC at 26 U.S.C. 5722 requires such persons to make reports as required by regulation. Under those authorities, the TTB regulations in 27 CFR part 44 require tobacco product and cigarette paper and tube manufacturers and export warehouse proprietors to report such removals on form TTB F 5200.14. Alternatively, under the alternate procedure described in TTB Industry Circular 2004–3, respondents may submit a Monthly Summary Report of such removals if records maintained at the respondent's premises document the export of each removal. Under this information collection, respondents also submit letterhead notices to modify previously submitted information, and they submit letterhead applications to obtain authorization to use an alternative Monthly Summary Report procedure. The collected information ensures the appropriate payment of tax under the IRC.

Current Actions: There are no program changes associated with this information collection, and TTB is submitting it for extension purposes only. As for adjustments, due to a change in agency estimates, TTB is decreasing the number of respondents, responses, and burden hour associated with this information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden

- *Number of Respondents:* 280.
- *Average Responses per Respondent:* 18.
- *Number of Responses:* 5,040.
- *Average per-Response Burden:* 1.85 hours.
- *Total Burden:* 9,324 hours.

OMB Control No. 1513–0030

Title: Claims—Alcohol, Tobacco, and Firearms Taxes.

TTB Form Number: TTB F 5620.8.

Abstract: The IRC at 26 U.S.C. 5008, 5056, 5370, and 5705 authorizes the Secretary to provide for claims for taxpayer relief from excise taxes paid on distilled spirits, wine, beer, and tobacco products lost or destroyed by theft or disaster, voluntarily destroyed, or returned or withdrawn from the market. The IRC at 26 U.S.C. 5044 also allows for the refund of tax for wine returned to bond. In addition, the IRC at 26 U.S.C. 5111–5114, authorizes the Secretary to issue drawback (refunds) for a portion of the excise taxes paid on distilled spirits used in the manufacture of certain nonbeverage products. Finally, the IRC at U.S.C. 6402–6404 provides that taxpayers may be refunded on certain overpayments, while section 6423 sets conditions on such claims for alcohol and tobacco excise taxes. Under those IRC authorities, the TTB regulations require taxpayers to make claims using form

TTB F 5620.8. On that form, the respondent states the amount of and the reasons and circumstances for the claim. This collected information is necessary to ensure the tax provisions of the IRC are appropriately applied as it allows TTB to determine if submitted claims meet the statutory and regulatory criteria.

Current Actions: There are no program changes or adjustments associated with this information collection, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits; Individuals or households; and Not-for profit institutions.

Estimated Annual Burden

- *Number of Respondents:* 5,000.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 5,000.
- *Average per-Response Burden:* 1 hour.
- *Total Burden:* 5,000 hours.

OMB Control No. 1513–0054

Title: Offer in Compromise of Liability Incurred under the Provisions of Title 26 U.S.C. Enforced and Administered by TTB; Collection Information Statements for Individuals and Businesses.

TTB Form Numbers: TTB F 5600.17, TTB F 5600.18, TTB F 5640.1.

Abstract: The IRC at 26 U.S.C. 7122 provides that the Secretary may compromise any civil or criminal case arising under it, including tax liabilities, in lieu of civil or criminal action. Under this authority, the TTB regulations require persons to submit offers in compromise for violations of the IRC on form TTB F 5640.1. Submitters use that form to identify the tax liabilities or violations being compromised, the amount of the compromise offer, and the reason for the offer. To support requests for installment payments of compromise offers, TTB may require individual and business respondents to supply information documenting financial hardship on TTB F 5600.17 and TTB F 5600.18, respectively. The collected information allows TTB to consider the offer in compromise in relation to the alleged violations of the law and the potential for a payment plan to address circumstances in which the individual or business is unable to pay an accepted offer in compromise immediately in full.

Current Actions: There are no program changes or adjustments associated with this information collection, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits; and Individuals or households.

Estimated Annual Burden

- *Number of Respondents:* 40.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 40.
- *Average per-Response Burden:* 2.5 hours.
- *Total Burden:* 90 hours.

OMB Control No. 1513–0055

Title: Offer in Compromise of Liability Incurred under the Federal Alcohol Administration Act.

TTB Form Number: TTB F 5640.2.

Abstract: The FAA Act (27 U.S.C. 201 *et seq.*) requires certain alcohol beverage industry members to obtain basic permits from the Secretary, and it prohibits unfair trade practices and deceptive advertising and labeling of alcohol beverages. Under 27 U.S.C. 207, violations of the Act are subject to civil and criminal penalties, but the Secretary may accept monetary compromise for such alleged violations. Under that authority, the TTB regulations provide that a proponent or their agent may submit an offer in compromise to resolve alleged FAA Act violations using form TTB F 5640.2. The form identifies the alleged violation(s) and violator(s), amount of the compromise offer, and the reason(s) for the offer. TTB uses the information to evaluate the adequacy of the compromise offer in relation to the alleged violation(s) of the FAA Act and to determine if it should accept the offer.

Current Actions: There are no program changes or adjustments associated with this information collection, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits; and Individuals or households.

Estimated Annual Burden

- *Number of Respondents:* 20.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 20.
- *Average per-Response Burden:* 2 hours.
- *Total Burden:* 40 hours.

OMB Control No. 1513–0090

Title: Excise Tax Return—Alcohol and Tobacco (Puerto Rico).

TTB Form Number: TTB F 5000.25.

Abstract: The IRC at 26 U.S.C. 5061(a) and 26 U.S.C. 5703(b) requires that excise taxes on alcohol and tobacco products be collected on the basis of a return, filed for the periods, at the times, and containing the information the Secretary requires by regulation. Under the IRC at 26 U.S.C. 7652(a), such taxes, at the same rates, are imposed on similar products manufactured in Puerto Rico and brought into the United States, and the majority of those taxes are subsequently transferred into the treasury of Puerto Rico. The TTB regulations in 27 CFR part 26 (for distilled spirits, wine, and beer) and part 41 (for tobacco products and cigarette papers and tubes), prescribe the use of TTB F 5000.25, Excise Tax Return—Alcohol and Tobacco (Puerto Rico) for the collection of the excise taxes imposed by 26 U.S.C. 7652(a). This collection is necessary to ensure the tax provisions of the IRC are appropriately applied.

Current Actions: There are no program changes or adjustments associated with this information collection, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits; Individuals and households.

Estimated Annual Burden

- *Number of Respondents:* 24.
- *Average Responses per Respondent:* 19.75.
- *Number of Responses:* 474.
- *Average per-Response Burden:* 0.75 hour.
- *Total Burden:* 356 hours.

OMB Control No. 1513–0112

Title: Special (Occupational) Tax Registration and Returns.

TTB Form Numbers: TTB F 5630.5a, TTB F 5630.d, and TTB F 5630.5t.

Abstract: Before July 1, 2008, various sections of chapter 51 of the IRC required alcohol industry members to register for and pay an annual special occupational tax (SOT). However, section 11125 of Public Law 109–59 permanently repealed, effective July 1, 2008, the SOT on alcohol beverage producers and marketers, non-beverage product manufacturers, tax-free alcohol users, and specially denatured spirits users and dealers, but any SOT liabilities incurred for periods before that date remain. Also, while most SOT requirements for the alcohol industry were repealed, 26 U.S.C. 5124 continues to require wholesale and retail alcohol dealers to register with the Secretary when commencing or ending business or when certain changes to existing registration information are necessary. In addition, the IRC at 26 U.S.C. 5731

and 5732 continues to require manufacturers of tobacco products and cigarette papers and tubes, as well as export warehouse proprietors, to register and pay an annual SOT by the use of a return. The registrations and SOT payments for such entities are due on or before the date of commencing business, and on or before July 1 of every year after that. Under the TTB regulations in 27 CFR part 31, alcohol industry members with pre-July 1, 2008, SOT liabilities use TTB F 5630.5a as the return for such liabilities, while wholesale and retail alcohol dealers register or report registration changes on TTB F 5630.5d. Under the TTB regulations in 27 CFR parts 40, 44, and 46, tobacco industry members use TTB F 5630.5t to register and pay SOT. This collection is necessary to ensure the registration and SOT provisions of the IRC are appropriately applied.

Current Actions: There are no program changes with this information collection, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is decreasing the number of respondents, responses, and burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits; Individuals or households; and Not-for-profit institutions.

Estimated Annual Burden

- *Number of Respondents:* 6,500.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 6,500.
- *Average per-Response Burden:* 25 minutes.
- *Total Burden:* 2,708 hours.

OMB Control No. 1513–0140

Title: Voluntary Chemist Certification Program Applications, Notices, and Records.

Abstract: TTB offers the Chemist Certification Program as a service to the alcohol beverage industry to facilitate export of beverage alcohol to foreign markets. Many countries that require testing as a condition of entry for alcohol beverages accept a report of analysis of those alcohol beverages from a TTB-certified chemist. This certification program ensures that chemists, enologists, brewers, and technicians generate quality data and have the required proficiencies to conduct the required chemical analyses. This information collection includes the application, notice, and recordkeeping requirements associated with the TTB voluntary chemist certification program, including letterhead applications for certification, submission of certification test results, requests for TTB-affirmed reports of analysis, and notices of changes in chemist employment place or status. Under this program, certified chemists and their laboratories must also maintain usual and customary records regarding all analytical results conducted under the TTB certification, and records related to laboratory equipment, quality control policies, procedures and systems, and analyst training and competence.

Current Actions: There are no program changes or adjustments associated with this information collection, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden

- *Number of Respondents:* 310.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 310.
- *Average per-Response Burden:* 1.33 hours.
- *Total Burden:* 412 hours.

Dated: November 12, 2021.

Amy R. Greenberg,

Director, Regulations and Rulings Division.

[FR Doc. 2021–25090 Filed 11–15–21; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Fee Schedule for the Transfer of U.S. Treasury Book-Entry Securities Held on the Fedwire Securities Service

AGENCY: Bureau of the Fiscal Service, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury (Treasury) is announcing a new fee schedule applicable to transfers of U.S. Treasury book-entry securities maintained on the Fedwire Securities Service (Fedwire) that occur on or after January 3, 2022.

DATES: Effective January 3, 2022.

FOR FURTHER INFORMATION CONTACT: Janeene Wilson, Bureau of the Fiscal Service, 304–480–6321.

SUPPLEMENTARY INFORMATION: Treasury has established a fee structure for the transfer of Treasury book-entry securities maintained on Fedwire. Treasury reassesses this fee structure periodically based on our review of the latest book-entry costs and volumes.

For each Treasury securities transfer or reversal sent or received on or after January 3, 2022, the basic fee will increase from $0.65 to $0.74. The Federal Reserve System also charges a funds movement fee for each of these transactions for the funds settlement component of a Treasury securities transfer.[1] The surcharge for an off-line Treasury book-entry securities transfer will increase from $70.00 to $80.00. Off-line refers to the sending and receiving of transfer messages to or from a Federal Reserve Bank by means other than on-line access, such as by written, facsimile, or telephone voice instruction. The basic transfer fee assessed to both sends and receives is reflective of costs associated with the processing of securities transfers. The off-line surcharge, which is in addition to the basic fee and the funds movement fee, reflects the additional processing costs associated with the manual processing of off-line securities transfers.

Treasury does not charge a fee for account maintenance, the stripping and reconstitution of Treasury securities, the wires associated with original issues, or interest and redemption payments. Treasury currently absorbs these costs.

The fees described in this notice apply only to the transfer of Treasury book-entry securities held on Fedwire. Information concerning fees for book-entry transfers of Government Agency securities, which are priced by the Federal Reserve, is set out in a separate **Federal Register** notice published by the Federal Reserve.

The following is the Treasury fee schedule that will take effect on January 3, 2022, for book-entry transfers on Fedwire:

TREASURY-FEDWIRE FEE SCHEDULE EFFECTIVE JANUARY 3, 2022

[In dollars]

	Fee
Basic Transfer Origination	0.74
Basic Transfer Received	0.74
Basic Reversal Origination ...	0.74
Basic Reversal Received	0.74
Off-line Origination and Receipt Surcharge	80.00

[1] The Board of Governors of the Federal Reserve System sets this fee separately from the fees assessed by Treasury. For a current listing of the Federal Reserve System's fees, please refer to *https://www.frbservices.org/financial-services/securities/index.html.*

Authority: 31 CFR 357.45.

Timothy E. Gribben,

Commissioner, Bureau of the Fiscal Service.

[FR Doc. 2021–24936 Filed 11–15–21; 8:45 am]

BILLING CODE 4810–AS–P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: November 18, 2021, 12:00 p.m. to 2:00 p.m., Eastern time.

PLACE: This meeting will be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll) or (ii) 1–877–853–5247 (US Toll Free) or 1–888–788–0099 (US Toll Free), Meeting ID: 976 6673 2184, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is *https://kellen.zoom.us/j/97666732184.*

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Education and Training Subcommittee (the ''Subcommittee'') will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Call to Order—Subcommittee Chair
The Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director
The UCR Executive Director will verify the publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Subcommittee Agenda and Setting of Ground Rules—Subcommittee Chair
For Discussion and Possible Subcommittee Action
The Agenda will be reviewed, and the Subcommittee will consider adoption.
Ground Rules
Subcommittee action only to be taken in designated areas on agenda.

IV. Review and Approval of Subcommittee Minutes from the October 7, 2021 Meeting—Subcommittee Chair
For Discussion and Possible Subcommittee Action
Draft minutes from the October 7, 2021 Subcommittee meeting via teleconference will be reviewed. The Subcommittee will consider action to approve.

V. Audit Module 2 Development Discussion—UCR Operations Manager
The UCR Operations Manager will discuss and provide updates on development of the Audit Module 2.

VI. Other Business—Subcommittee Chair
The Subcommittee Chair will call for any other items Subcommittee members would like to discuss.

VII. Adjournment—Subcommittee Chair
The Subcommittee Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, November 11, 2021 at: *https://plan.ucr.gov.*

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2021–25057 Filed 11–12–21; 11:15 am]

BILLING CODE 4910–YL–P

DEPARTMENT OF VETERANS AFFAIRS

Veterans and Community Oversight and Engagement Board, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act (FACA), 5 U.S.C. app. 2, that the Veterans and Community Oversight and Engagement Board will meet virtually on December 2, 2021. The meeting will begin and end as follows:

Date	Time
December 2, 2021	3:00 p.m. to 7:00 p.m. Eastern Standard Time (EST).

The meeting is open to the public and will be recorded. Members of the public can attend the meeting by registering at the link below:*https://veteransaffairs.webex.com/veteransaffairs/onstage/g.php?MTID=e315893bd540f26b301ecaeeb04374025.*

The Board was established by the West Los Angeles Leasing Act of 2016 on September 29, 2016. The purpose of the Board is to provide advice and make recommendations to the Secretary of Veterans Affairs on: Identifying the goals of the community and Veteran partnership; improving services and outcomes for Veterans, members of the Armed Forces, and the families of such Veterans and members; and on the implementation of the Draft Master Plan approved by the Secretary on January 28, 2016, and on the creation and implementation of any successor master plans.

On Dec 2, the agenda will include opening remarks from the Committee Chair, Executive Sponsor, and other VA officials. There will be a comprehensive briefing from the Veterans Administration Greater Los Angeles Healthcare System (VAGLAHS) on Master Plan 2022 timeline and activities, Current and Future project status, and timeline, to include a side-by-side comparison of Master Pan 2016 and Master Plan 2022. The Board's Services and Outcome Subcommittee Master Plan will present a recommendation that introduces a dashboard to track Homeless Veterans, HUD VASH voucher utilization, and vacant master-leased properties.

A public comment session will occur from 4:10 p.m. to 5:10 p.m. Individuals wishing to make public comments are required to register during the WEBEX registration process. In the interest of time management, speakers will be held to a 5-minute time limit and selected in the order of event registration. If time expires and your name was not selected, or you did not register to provide public comment and would like to do so, you are asked to submit public comments via email at *VEOFACA@va.gov* for inclusion in the official meeting record.

To attend the meeting, use the registration instructions—Registration Instructions: Select the ''Register'' hyperlink in event status or the ''Register'' button located bottom center of the page. Attendees will then be asked to identify themselves by first name, last name, email address, affiliation (if any) and interest in making a public comment. Please select ''Submit'' to finish registration. You will receive a confirmation email from WEBEX shortly after registration. The confirmation email will include a calendar event invitation and instructions to join the meeting via web browser or telephone. Attempts to join the meeting will not work until the host opens the meeting approximately ten minutes prior to start time.

Any member of the public seeking additional information should contact

Mr. Eugene W. Skinner Jr. at (202) 631–7645 or *Eugene.Skinner@va.gov.*

Dated: November 10, 2021.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2021–24975 Filed 11–15–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0891]

Agency Information Collection Activity: COVID–19 Refund Modification

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 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. 2900–0891.''

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0891'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 CFR 36.4338(a).

Title: COVID–19 Refund Modification.

OMB Control Number: 2900–0891.

Type of Review: Extension of a currently approved collection.

Abstract: VA is temporarily expanding the list of loan modification options available to servicers that do not require VA's prior approval to include a new loan modification, the COVID–19 Refund Modification, to assist certain COVID-impacted veterans as they exit a COVID–19 forbearance. Under 38 U.S.C. 3720(a)(2), Congress has provided the Secretary with discretion ''[n]otwithstanding the provisions of any other law'' to set the terms and conditions to which the Secretary will consent to loan modifications. Additionally, while VA has outlined in regulation at 38 CFR 36.4315(a) the terms of loan modifications that do not require prior VA approval, VA may waive a regulatory requirement if VA finds the interest of the Government are not adversely affected and such waiver would relieve undue prejudice to a debtor, holder, or other person without impairing the vest rights of any person affected. 38 CFR 36.4338(a).

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 86 FR 50210 on September 7, 2021, pages 50210 and 50211.

Affected Public: Individuals or Households.

Estimated Annual Burden: 25,800.

Estimated Average Burden per Respondent: 90 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 17,200.

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. 2021–25007 Filed 11–15–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

National Research Advisory Council, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the National Research Advisory Council will hold a meeting on Wednesday, December 8, 2021, by Webex. The teleconference number is 1–404–397–1596, conference ID 199 811 6717 or the meeting link is *https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=mee580294d1ca4b86e69b617fd028f134.* The meeting will convene at 11:00 a.m. and end at 2:00 p.m. Eastern daylight time. This meeting is open to the public.

The purpose of the National Research Advisory Council is to advise the Secretary on research conducted by the Veterans Health Administration, including policies and programs targeting the high priority of Veterans' health care needs.

On December 8, 2021, the agenda will include a discussion of fiscal year 2021 accomplishments in review; follow up discussion of diversity, equity, and inclusion activities in response to the NRAC recommendations; and discussion of subcommittee activities. No time will be allocated at this meeting for receiving oral presentations from the public. Members of the public wanting to attend, have questions or presentations to present may contact Rashelle Robinson, Designated Federal Officer, Office of Research and Development (14RD), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, at 202–443–5768, or *Rashelle.robinson@va.gov* no later than close of business on December 3, 2021. All questions and presentations will be presented during the public comment section of the meeting. Any member of the public seeking additional information should contact Rashelle Robinson at the above phone number or email address noted above.

Dated: November 9, 2021.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2021–24893 Filed 11–15–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0892]

Agency Information Collection Activity Under OMB Review: Reimbursement of Preparatory (PREP) Course for Licensing or Certification Test

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. 2900–0892.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0892'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: Section 5, Public Law 116–154.

Title: Reimbursement of Preparatory (PREP) Course for Licensing or Certification.

OMB Control Number: 2900–0892.

Type of Review: Revision of a currently approved collection.

Abstract: The information collected on the VA Form 22–10272 will be utilized to permit beneficiaries to apply for reimbursement of approved preparatory courses taken to assist with preparing for a Licensing or Certification Test. VA will use data from this information collection to ensure eligible Post 9/11 GI Bill (chapter 33) and Survivors' and Dependents' Educational Assistance (DEA or chapter 35) can receive payment for attending the approved preparatory course. Without the utilization of this form, eligible beneficiaries will not be able to apply for the reimbursement they may be rightly entitled to pursuant to 38 U.S. Code 3315B.

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 86 FR 50211 on September 7, 2021.

Affected Public: Individuals or Households.

Estimated Annual Burden: 71 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: Occasionally.

Estimated Number of Respondents: 285.

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. 2021–24939 Filed 11–15–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Minority Veterans, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App 2., that the Advisory Committee on Minority Veterans will virtually meet on December 7–9, 2021. The meeting sessions will begin and end as follows:

Dates	Times
December 7, 2021	11:00 a.m.–3:00 p.m.—Eastern Standard Time (EST).
December 8, 2021	11:00 a.m.–3:00 p.m. EST.
December 9, 2021	11:00 a.m.–3:00 p.m. EST.

This meeting is open to the public. To access the meeting, please click the link: Adobe Connect: *http://va-eerc-ees.adobeconnect.com/cmv_admin/.*

The purposes of the Committee are to: Advise the Secretary on the administration of VA benefits and services to minority Veterans; assess the needs of minority Veterans; and evaluate whether VA compensation, medical and rehabilitation services, outreach, and other programs are meeting those needs. The Committee makes recommendations to the Secretary regarding such activities.

On December 7, the Committee will receive briefings and updates from the Center for Minority Veterans, National Cemetery Administration, Veterans Experience Office, National Center for Veterans Analysis and Statistics, Office of Tribal Government Relations, and Veterans Benefits Administration. On December 8, the Committee will receive briefings and updates from the Board of Veterans Appeals, Veterans Health Administration, Center for Women Veterans, Mental Health, Inclusion, Diversity, Equity and Access (IDEA) Task Force, Office of Rural Health and Office of Health Equity. On December 9, the Committee will receive briefings and updates on Office of Diversity & Inclusion, Senior Advisor for Pacific Strategies and ex officio updates. The Committee will then hold a leadership exit briefing with Veterans Benefits Administration, Veterans Health Administration and National Cemetery Administration. The Committee will receive public comments from 1:00 p.m. to 1:15 p.m. The Committee will conduct an after-action review.

Individuals who wish to provide public comment are invited to submit a 1–2-page summary of their comments no later than November 29, 2021 for inclusion in the official meeting record. Members of the public may also submit written statements for the Committee's review to Ms. Juanita Mullen, at *Juanita.Mullen@va.gov.* Any member of the public seeking additional information should contact Ms. Juanita Mullen or Mr. Dwayne Campbell at (202) 461–6191.

Dated: November 9, 2021.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2021–24909 Filed 11–15–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Women Veterans, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. app 2, that the Advisory Committee on Women Veterans will conduct a virtual meeting on December 14–16, 2021. The meeting will begin at 10:00 a.m. Eastern Standard Time (EST) and end 1:00 p.m. EST each day.

Date	Time	Location
December 14, 2021	10:00 a.m.–1:00 p.m. EST	See WebEx link and call-in information below.
December 15, 2021	10:00 a.m.–1:00 p.m. EST	See WebEx link and call-in information below.
December 16, 2021	10:00 a.m.–1:00 p.m. EST	See WebEx link and call-in information below.

The meeting sessions are open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs regarding the needs of women Veterans with respect to health care,

rehabilitation, compensation, outreach, and other programs and activities administered by VA designed to meet such needs. The Committee makes recommendations to the Secretary regarding such programs and activities.

The agenda will include updates from VA's Administrations and Staff Offices, updates on report recommendations, as well as briefings on other issues impacting women Veterans.

No time will be allocated at this meeting for receiving oral presentations from the public. Interested parties should provide written comments for review by the Committee to Ms. Shannon L. Middleton at *00W@mail.va.gov* no later than December 6, 2021. Any member of the public who wishes to participate in the virtual meeting may use the following WebEx link: *https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=m8545cf5df8c7b3b576baa1032fe90035.* To join by phone: 1–833–558–0712 (toll free); mobile device: 1–404–397–1596, meeting number/access code: 2763 047 1516.

Dated: November 10, 2021.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2021–24972 Filed 11–15–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–NEW]

Agency Information Collection Activity: Suicide Prevention 2.0 Program—Community Opinion Survey

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Health Administration (VHA), 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 extension 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 January 18, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Janel Keyes, Office of Regulations, Appeals, and Policy (10BRAP), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *Janel.Keyes@va.gov.* Please refer to ''OMB Control No. 2900–NEW'' 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), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–NEW'' 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, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA'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: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Suicide Prevention 2.0 Program—Community Opinion Survey.

OMB Control Number: 2900–NEW.

Type of Review: New collection.

Abstract: Legal authority for this data collection is found under 38 U.S.C., Part I, Chapter 5, Section 527, which authorizes the collection of data that will allow measurement and evaluation of VA Programs, the goal of which is improved health care for veterans. The information will be used to accomplish three aims: (1) Collect baseline data on the knowledge and attitudes of adult US citizens living in specified communities about veterans, veteran suicide, and resources available to veterans to reduce suicide, prior to the implementation of suicide prevention programs; (2) collect follow-up data in the same communities to assess whether those knowledge and attitudes have changed over time; and (3) determine whether the programs and policies implemented by a community resulted in positive change in knowledge and attitudes.

The data will be utilized by the Office of Mental Health and Suicide Prevention in VA Central Office to measure the return on investment of significant resources that have been invested to support communities in their efforts to reduce veteran suicide. Specifically, the Community-Based Interventions (CBI) arm of VA's ''Suicide Prevention 2.0'' (SP2.0) program has launched two different initiatives whose goals are to increase the successful implementation of best practices to prevent veteran suicide in local communities. The data will allow VA to measure a baseline level of expected outcomes, follow-up levels, and explore the role of new programs in any changes, as well as inform program planning and evaluation.

In addition, the data collected will be used by State teams that are engaged in the Governor's Challenge (GC) initiative. GC is one of the initiatives supported by SP2.0 and is structured so that State teams are provided training and technical assistance by VA to expand their efforts to implement suicide prevention programs in their State. This data collection will assist the State teams to assess the effects of their new programming or policies.

Affected Public: Individuals or households.

Estimated Annual Burden: 2,500 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: Once annually.

Estimated Number of Respondents: 10,000.

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. 2021–24970 Filed 11–15–21; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 86 Tuesday,

No. 218 November 16, 2021

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 416, 419, et al.

45 CFR Part 180

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 416, 419, and 512

Office of the Secretary

45 CFR Part 180

[CMS–1753–FC]

RIN 0938–AU43

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2022 based on our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. Also, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program, updates Hospital Price Transparency requirements, and updates and refines the design of the Radiation Oncology Model.

DATES:

Effective date: The provisions of the final rule with comment are effective January 1, 2022.

Comment period: To be assured consideration, comments on the payment classifications assigned to the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes in this final rule with comment period (CMS–1753–FC) must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on December 2, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1753–FC.

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 submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

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–1753–FC, P.O. Box 8010, Baltimore, MD 21244–1810.

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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1753–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov.*

Ambulatory Surgical Center (ASC) Payment System, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov* or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov.*

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov.*

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Cyra Duncan via email *Cyra.Duncan@cms.hhs.gov.*

Blood and Blood Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov.*

Cancer Hospital Payments, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov.*

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email at *Chuck.Braver@cms.hhs.gov.*

Comment Solicitation on Temporary Policies for the PHE for COVID–19, contact Emily Yoder via email at *Emily.Yoder@cms.hhs.gov* or Abigail Cesnik via email at *Abigail.Cesnik@cms.hhs.gov.*

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Au'Sha Washington via email at *AuSha.Washington@cms.hhs.gov.*

Comprehensive APCs (C–APCs), contact Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov.*

Hospital Inpatient Quality Reporting Program—Administration Issues, contact Julia Venanzi, *julia.venanzi@cms.hhs.gov.*

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Shaili Patel via email *Shaili.Patel@cms.hhs.gov.*

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Janis Grady via email *Janis.Grady@cms.hhs.gov.*

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Allison Bramlett via email at *Allison.Bramlett@cms.hhs.gov,* or Emily Yoder via email at *Emily.Yoder@cms.hhs.gov.*

Hospital Price Transparency, contact the Hospital Price Transparency email box at *PriceTransparencyHospitalCharges@cms.hhs.gov.*

Inpatient Only (IPO) Procedures List, contact Au'Sha Washington via email at *Ausha.Washington@cms.hhs.gov*, or Allison Bramlett at *Allison.Bramlett@cms.hhs.gov*, or Abigail Cesnik at *Abigail.Cesnik@cms.hhs.gov.*

Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2022 and Subsequent Years (2-Midnight Rule), contact Abigail Cesnik via email at *Abigail.Cesnik@cms.hhs.gov.*

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov.*

No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov.*

OPPS Brachytherapy, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov.*

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email at *Erick.Chuang@cms.hhs.gov,* or Scott Talaga via email at *Scott.Talaga@cms.hhs.gov,* or Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov.*

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov,* or Gil Ngan via email at *Gil.Ngan@cms.hhs.gov,* or Cory Duke via email at *Cory.Duke@cms.hhs.gov,* or Au'Sha Washington via email at *Ausha.Washington@cms.hhs.gov.*

OPPS New Technology Procedures/Services, contact the New Technology

APC mailbox at *NewTechAPCapplications@cms.hhs.gov.*

OPPS Packaged Items/Services, contact Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov* or Cory Duke via email at *Cory.Duke@cms.hhs.gov.*

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at *DevicePTapplications@cms.hhs.gov.*

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email at *Marina.Kushnirova@cms.hhs.gov.*

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at *PHPPaymentPolicy@cms.hhs.gov.*

RO Model, contact *RadiationTherapy@cms.hhs.gov* or at 844–711–2664, Option 5.

Skin Substitutes, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov.*

Supervision of Outpatient Therapeutic Services in Hospitals and CAHs, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov.*

All Other Issues Related to Hospital Outpatient Payments Not Previously Identified, contact the OPPS mailbox at *OutpatientPPS@cms.hhs.gov.*

All Other Issues Related to the Ambulatory Surgical Center Payments Not Previously Identified, contact the ASC mailbox at *ASCPPS@cms.hhs.gov.*

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 individual will take actions to harm the 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.

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS website. The Addenda relating to the OPPS are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.*

The Addenda relating to the ASC payment system are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.*

Current Procedural Terminology (CPT) Copyright Notice

Table of Contents

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this final rule with comment period, we are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2022. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments that take into account changes in medical practices, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i)(D)(v) of the Act, we annually review and update the ASC payment rates. This final rule with comment period also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. We describe these and various other statutory authorities in the relevant sections of this final rule with comment period. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, Hospital Price Transparency requirements, and the design of the Radiation Oncology Model.

2. Summary of the Major Provisions

• *OPPS Update:* For 2022, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.0 percent. This increase factor is based on the proposed hospital inpatient market basket percentage increase of 2.7 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS) reduced by a proposed productivity adjustment of 0.7 percentage point. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for calendar year (CY) 2022 would be approximately $82.078 billion, an increase of approximately $5.913 billion compared to estimated CY 2022 OPPS payments.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9804 to the OPPS payments and copayments for all applicable services.

• *Data used in CY 2022 OPPS/ASC Ratesetting:* To set CY 2022 OPPS and ASC payment rates, we would normally use the most updated claims and cost report data available. However, because the CY 2020 claims data include services furnished during the COVID–19 PHE, which significantly affected outpatient service utilization, we have determined that CY 2019 data would better approximate expected CY 2022 outpatient service utilization than CY 2020 data. As a result, we are utilizing CY 2019 data to set CY 2022 OPPS and ASC payment rates.

• *Partial Hospitalization Update:* For CY 2022, we are using the CMHC and hospital-based PHP (HB PHP) geometric mean per diem costs, consistent with existing methodology, but with a cost floor that will maintain the per diem costs finalized in CY 2021. We are also using the CY 2019 claims and cost report data for each provider type, consistent with the use of claims and cost report data prior to the PHE within the broader CY 2022 OPPS ratesetting.

• *Changes to the Inpatient Only (IPO) List:* For 2022, we are finalizing our proposal with modification to pause the elimination of the IPO list and add back to the IPO list the services removed in 2021, except for CPT code 22630 (Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar); CPT code 23472 (Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (for example, total shoulder))); CPT code 27702 (Arthroplasty, ankle; with implant (total ankle)) and their corresponding anesthesia codes: CPT code 00630 (Anesthesia for procedures in lumbar region; not otherwise specified), CPT code 00670 (Anesthesia for extensive spine and spinal cord procedures (*e.g.,* spinal instrumentation or vascular procedures)); CPT code 01638 (Anesthesia for open or surgical arthroscopic procedures on humeral

head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; total shoulder replacement); and CPT 01486 (Anesthesia for open procedures on bones of lower leg, ankle, and foot; total ankle replacement). We are also classifying CPT code 0643T (Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach) as an inpatient only procedure. We are finalizing our proposal to amend the regulation at § 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a 3-year transition and to codify our five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation in a new § 419.23.

• *Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years (2-Midnight Rule):* For CY 2022, we are finalizing a policy to exempt procedures that are removed from the inpatient only (IPO) list under the OPPS beginning on or after January 1, 2022, from site-of-service claim denials, Beneficiary and Family-Centered Care Quality Improvement Organization (BFCC–QIO) referrals to Recovery Audit Contractor (RAC) for persistent noncompliance with the 2-midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service) for a time period of 2 years.

• 340B-*Acquired Drugs:* For CY 2022, we are continuing our current policy of paying an adjusted amount of ASP minus 22.5 percent for drugs and biologicals acquired under the 340B program. We are continuing to exempt Rural SCHs, PPS-exempt cancer hospitals and children's hospitals from our 340B payment policy.

• *Device Pass-Through Payment Applications:* For CY 2022, we received eight applications for device pass-through payments. One of these applications received preliminary approval for pass-through payment status through our quarterly review process. We solicited public comment on all eight of these applications and are making final determinations on these applications in this CY 2022 OPPS/ASC final rule with comment period.

• *Equitable Adjustment for Device Category, Drugs, and Biologicals with Expiring Pass-through Status:* As a result of our proposal to use CY 2019 claims data, rather than CY 2020 claims data, to inform CY 2022 ratesetting, we are using our equitable adjustment authority under 1833(t)(2)(E) to provide up to four quarters of separate payment for 27 drugs and biologicals and one device category whose pass-through payment status will expire between December 31, 2021 and September 30, 2022.

• *Cancer Hospital Payment Adjustment:* For CY 2022, we are continuing to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. However, section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, we are using a target PCR of 0.89 to determine the CY 2022 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.89 for each cancer hospital.

• *ASC Payment Update:* For CYs 2019 through 2023, we adopted a policy to update the ASC payment system using the hospital market basket update. Using the hospital market basket methodology, for CY 2022, we are increasing payment rates under the ASC payment system by 2.0 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a hospital market basket percentage increase of 2.7 percent reduced by a productivity adjustment of 0.7 percentage point. Based on this update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2022 would be approximately 5.41 billion, an increase of approximately 40 million compared to estimated CY 2021 Medicare payments.

• *ASC Payment Policy for Non-Opioid Pain Management Drugs and Biologicals under Section 6082 of the SUPPORT Act (Section 1833(t)(22) of the Social Security Act):* Under section 1833(t)(22)(A) of the Act, the Secretary was required to conduct a review (part of which may include a request for information) of payments for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. Section 1833(t)(22)(A)(ii) provides that the Secretary may, as the Secretary determines appropriate, conduct subsequent reviews of such payments.

In accordance with our review and comments from stakeholders, for CY 2022, we are finalizing our proposal to modify the current non-opioid pain management payment policy and regulatory text to require that evidence-based non-opioid alternatives for pain management must be approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act, under an abbreviated new drug application under section 505(j), or, in the case of a biological product, be licensed under section 351 of the Public Health Service Act. We further proposed that the drug or biological must also have an FDA-approved indication for pain management or analgesia and have a per-day cost in excess of the OPPS drug packaging threshold, which is finalized at $130 for CY 2022 and described in section V.B.1.a. of this final rule with comment period, to qualify for separate payment in the ASC setting. We appreciate the comments received on our multiple comment solicitations. We are not finalizing any policy modifications or additional criteria as a result of these comments but will take this information into consideration for future notice and comment rulemaking.

For CY 2022, in accordance with our finalized criteria, CMS review, and stakeholder comments, we will pay separately in the ASC setting for four drugs that are non-opioid pain management drugs that function as surgical supplies.

• *Changes to the List of ASC Covered Surgical Procedures:* For CY 2022, we are reinstating the ASC Covered Procedures List (CPL) criteria that were in effect in CY 2020 and removing several of the procedures that were added to the ASC CPL in CY 2021. We requested comments on whether any of the procedures that we proposed to remove from the ASC CPL in CY 2021 met the CY 2020 criteria that we proposed to reinstate. After reviewing these recommendations, we determined that a total of six procedures should either remain on or be added to the CPL We are also finalizing our proposal to adopt a nomination process, under which stakeholders may nominate procedures they believe meet the requirements to be added to the ASC CPL. CMS will provide subregulatory guidance on the nomination process in early 2022, with procedure nominations due in March 2022, and the formal nomination process beginning in CY 2023.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we proposed changes for the CY 2023, CY 2024, CY 2025, and CY 2026 payment determinations and subsequent years in the CY 2022 OPPS/ASC proposed rule (86 FR 42018). In this final rule, we are finalizing our proposals to: (1) Remove the OP–02: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival measure beginning with the CY 2025 payment determination; (2) remove the OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention measure beginning with the CY 2025 payment determination; (3) adopt OP–38: COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure beginning with the CY 2024 payment determination; (4) adopt OP–39: The Breast Screening Recall Rates measure beginning with the CY 2023 payment determination; (5) adopt OP–40: The ST-Segment Elevation Myocardial Infarction (STEMI) electronic clinical quality measure (eCQM) beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination; and (6) restart reporting of the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures beginning with voluntary reporting during the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination. We are finalizing as proposed the data submission requirements for the OAS CAHPS Survey-based measures and the COVID–19 Vaccination Coverage Among HCP measure (OP–38). Similarly, we are finalizing as proposed the data submission and certification requirements for eCQMs and expanding our Extraordinary Circumstances Exemption (ECE) policy to these measures.

Beginning with the CY 2024 payment determination, we are finalizing as proposed three updates to our validation requirements to: (1) Use electronic file submissions for chart-abstracted measure medical record requests; (2) change the chart validation requirements and methods; and (3) update the targeting criteria. In the CY 2022 OPPS/ASC proposed rule (86 FR 42018) we requested comment from stakeholders on: (1) The potential future development and inclusion of a patient-reported outcomes measure following elective total hip and/or total knee arthroplasty (THA/TKA); (2) the possibility of expanding our current disparities methods to include reporting by race and ethnicity; and (3) the possibility of hospital collection of standardized demographic information for quality reporting and measure stratification. We also requested feedback across programs on potential actions and priority areas that would enable the continued transformation of our quality measurement toward greater digital capture of data and use of the FHIR standard.

We are finalizing with modification, our proposal to make mandatory the reporting of the OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure. We are finalizing to make reporting of this measure mandatory beginning with the CY 2027 payment determination, instead of the CY 2025 payment determination.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we proposed changes for the CY 2024, CY 2025, and CY 2026 payment determinations and subsequent years in the CY 2022 OPPS/ASC proposed rule (86 FR 42018). For the ASCQR Program measure set, we are finalizing our proposals to: (1) Adopt ASC–20: COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2024 payment determination; and (2) resume data collection for four measures beginning with the CY 2025 payment determination: (a) ASC–1: Patient Burn; (b) ASC–2: Patient Fall; (c) ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and (d) ASC–4: All-Cause Hospital Transfer/Admission. We are also finalizing as proposed the data submission requirements for the OAS CAHPS Survey-based measures and the COVID–19 Vaccination Coverage Among HCP measure (ASC–20).

We are finalizing, with modification, the proposal to require the ASC–15a–e: OAS CAHPS Survey-based measures with voluntary reporting beginning with the CY 2024 reporting period and mandatory reporting beginning with the CY 2025 reporting period/CY 2027 payment determination.

We are also finalizing with modification the proposal to require the ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure. We are finalizing mandatory reporting of this measure beginning with the CY 2027 payment determination, instead of the CY 2025 payment determination.

In the CY 2022 OPPS/ASC proposed rule (86 FR 42018) we requested stakeholder comment on: (1) The potential future development and inclusion of a patient-reported outcomes measure following elective THA/TKA; (2) potential measurement approaches or social risk factors that influence health disparities in the ASC setting; and (3) the future inclusion of a measure to assess pain management surgical procedures performed in ASCs. We also requested feedback across programs on potential actions and priority areas that would enable the continued transformation of our quality measurement toward greater digital capture of data and use of the FHIR standard.

• *Hospital Inpatient Quality Reporting (IQR) Program Update:* In the CY 2022 OPPS/ASC proposed rule (86 FR 25549 through 25628) we requested information from stakeholders on potential measure updates on reporting and submission requirements for the Safe Use of Opioids—Concurrent Prescribing eCQM.

• *Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges:* We are amending several hospital price transparency policies codified at 45 CFR part 180 in order to encourage compliance. We are: (1) Increasing the amount of the penalties for noncompliance through the use of a scaling factor based on hospital bed count; (2) deeming state forensic hospitals that meet certain requirements to be in compliance with the requirements of 45 CFR part 180; and (3) finalizing a requirement that the machine-readable file be accessible to automated searches and direct downloads. In addition, we clarify the expected output of hospital online price estimator tools when hospitals choose to use an online price estimator tool in lieu of posting its standard charges for the required shoppable services in a consumer-friendly format.

• *Radiation Oncology Model (RO Model):* Section 133 of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116–260), enacted on December 27, 2020, includes a provision that prohibits the RO Model from beginning before January 1, 2022. This law supersedes the RO Model delayed start date established in the CY 2021 OPPS/ASC final rule with comment period. We are finalizing proposed provisions related to the additional delayed implementation of the RO Model due to the CAA, 2021, as well as modifications to certain RO Model policies not related to the delay.

• *Comment Solicitation on Temporary Policies for the PHE for COVID–19:* In response to the COVID–19 pandemic, CMS undertook emergency rulemaking to implement a number of flexibilities to address the pandemic, such as preventing spread of the infection and supporting diagnosis of COVID–19. While many of these flexibilities will expire at the conclusion of the PHE, we sought comment on whether there are certain policies that should be made permanent. Specifically, we sought comment on services furnished by hospital staff to beneficiaries in their homes through use of communication technology, direct supervision when the supervising practitioner is available through two-way, audio/video communication technology, and a code and payment for COVID–19 specimen collection. We will consider comments received for future rulemaking.

• *Changes to Beneficiary Coinsurance for Colorectal Cancer Screening Test:* Section 122 of the Consolidated Appropriations Act (CAA) of 2021 amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We are finalizing our proposal that all surgical services furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy could be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test for purposes of determining the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter.

3. Summary of Costs and Benefits

In sections XXIV. and XXV. of this final rule with comment period, we set forth a detailed analysis of the regulatory and federalism impacts that the changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of All OPPS Changes

Table 84 in section XXIV.C. of this final rule with comment period displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2022 compared to all estimated OPPS payments in CY 2021. We estimate that the policies in this final rule with comment period will result in a 1.6 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2022, including beneficiary cost-sharing, to the approximately 3,659 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) will increase by approximately $1.3 billion compared to CY 2021 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure we adopted beginning in CY 2011, and basing payment fully on the type of provider furnishing the service, we estimate a 1.1 percent increase in CY 2022 payments to CMHCs relative to their CY 2021 payments.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the FY 2022 IPPS final rule wage indexes will result in no change for urban hospitals under the OPPS and no change for rural hospitals. These wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data, with updates, as discussed in section II.C. of this final rule with comment period.

c. Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our CY 2022 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not making any change in policies for determining the rural hospital payment adjustments. While we are implementing the reduction to the cancer hospital payment adjustment for CY 2022 required by section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act, the target payment-to-cost ratio (PCR) for CY 2021 is 0.89, equivalent to the 0.89 target PCR for CY 2021, and therefore has no budget neutrality adjustment.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2022 OPPS/ASC, we are establishing an OPD fee schedule increase factor of 2.0 percent and applying that increase factor to the conversion factor for CY 2022. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals will experience an increase in payments of approximately 2.1 percent and that rural hospitals will experience an increase in payments of 2.3 percent. Classifying hospitals by teaching status, we estimate nonteaching hospitals will experience an increase in payments of 2.2 percent, minor teaching hospitals will experience an increase in payments of 2.2 percent, and major teaching hospitals will experience an increase in payments of 1.8 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership will experience an increase of 2.2 percent in payments, while hospitals with government ownership would experience an increase of 1.7 percent in payments. We estimate that hospitals with proprietary ownership will experience an increase of 2.3 percent in payments.

e. Impacts of the ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2022 payment rates, compared to estimated CY 2021 payment rates, generally ranges between an increase of 2 and 4 percent, depending on the service, with some exceptions. We estimate the impact of applying the hospital market basket update to ASC payment rates will increase payments by $80 million under the ASC payment system in CY 2022.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016; the Consolidated Appropriations Act, 2018 (Pub. L. 115–141), enacted on March 23, 2018; the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), enacted on October 24, 2018; the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), enacted on December 20, 2019; the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136), enacted on March 27, 2020; and the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), enacted on December 27, 2020.

Under the OPPS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this final rule with comment period. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017 by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21)). We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are

excluded from payment under the OPPS. These excluded hospitals are:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and
- Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.*

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and advise the Secretary concerning) the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act (the PHS Act), which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel—

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- May advise on OPPS APC rates for ASC covered surgical procedures;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 20, 2020, for a 2-year period.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.*

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 31, 2020. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, new members, and any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). In CY 2018, we published a **Federal Register** notice requesting nominations to fill vacancies on the Panel (83 FR 3715). As published in this notice, CMS is accepting nominations on a continuous basis.

In addition, the Panel has established an administrative structure that, in part, currently includes the use of three subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The three current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises and provides recommendations to the Panel on the appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made;
- Data Subcommittee, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them; and
- Visits and Observation Subcommittee, which reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS.

Each of these workgroup subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 23, 2021, meeting that the subcommittees continue. We accepted this recommendation.

For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS website mentioned earlier in this

section, and the FACA database at *http://facadatabase.gov.*

F. Public Comments Received in Response to the CY 2022 OPPS/ASC Proposed Rule

We received approximately 18,864 timely pieces of correspondence on the CY 2022 OPPS/ASC proposed rule that appeared in the **Federal Register** on August 4, 2021 (86 FR 42018). We note that we received some public comments that were outside the scope of the CY 2022 OPPS/ASC proposed rule. Out-of-scope-public comments are not addressed in this CY 2022 OPPS/ASC final rule with comment period. Summaries of those public comments that are within the scope of the proposed rule and our responses are set forth in the various sections of this final rule with comment period under the appropriate headings.

G. Public Comments Received on the CY 2021 OPPS/ASC Final Rule With Comment Period

We received approximately 32 timely pieces of correspondence on the CY 2021 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on December 2, 2020 (85 FR 85866), most of which were outside of the scope of the final rule. In-scope comments related to the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes (identified with comment indicator ''NI'' in OPPS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule).

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Use of CY 2019 Data in the CY 2022 OPPS Ratesetting

We primarily use two data sources in OPPS ratesetting: Claims data and cost report data. Our goal is always to use the best available data overall for ratesetting. Ordinarily, the best available full year of claims data would be the data from the year two years prior to the calendar year that is the subject of the rulemaking. As discussed in further detail in Section X.E. of the CY 2022 OPPS/ASC proposed rule (86 FR 42188 through 42190), given our concerns with CY2020 data as a result of the COVID–19 PHE we proposed to generally use CY 2019 claims data and the data components related to it in establishing the CY 2022 OPPS. As discussed in further detail in Section X.E. of this final rule with comment period, we are finalizing our proposal to generally use CY 2019 claims data and the data components related to it in establishing the CY 2022 OPPS.

b. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

For the CY 2022 OPPS, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2022, and before January 1, 2023 (CY 2022), using the same basic methodology that we described in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85873), using CY 2019 claims data. That is, we proposed to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2022, we began with approximately 180 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2019, and before January 1, 2020, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 93 million final action claims to develop the proposed CY 2022 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for the CY 2022 OPPS/ASC proposed rule on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

Addendum N to the CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*) includes the proposed list of bypass codes for CY 2022. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2019 and, therefore, includes codes that were in effect in CY 2019 and used for billing. We proposed to retain deleted bypass codes on the proposed CY 2022 bypass list because these codes existed in CY 2019 and were covered OPD services in that period, and CY 2019 claims data were used to calculate proposed CY 2022 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to the proposed rule. HCPCS codes that we proposed to add for CY 2022 are identified by asterisks (*) in the fourth column of Addendum N.

We did not receive any public comments on our general proposal to recalibrate the relative payment weights for each APC based on claims and cost report data for HOPD services or on our proposed bypass code process. We are adopting as final the proposed ''pseudo'' single claims process and the final CY 2022 bypass list of 173 HCPCS codes, as displayed in Addendum N to this final rule with comment period (which is available via the internet on the CMS website). For this final rule with comment period, for the purpose of recalibrating the final APC relative payment weights for CY 2022, we used approximately 93 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2019, and before January 1, 2020. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this final rule with comment period on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

c. Calculation and Use of Cost-to-Charge Ratios (CCRs)

For 2022, in the CY 2022 OPPS/ASC proposed rule (86 FR 42046) we proposed to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the CY 2022 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2019 claims data by comparing these claims data to hospital

cost reports available for the CY 2021 OPPS/ASC final rule with comment period ratesetting, which, in most cases, are from CY 2019. For the proposed CY 2022 OPPS payment rates, we used the set of CY 2019 claims processed through June 30, 2020. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2019 (the year of claims data we used to calculate the proposed CY 2022 OPPS payment rates) and updates to the National Uniform Billing Committee (NUBC) 2020 Data Specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

In accordance with our longstanding policy, we calculate CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.a.(1) of the CY 2022 OPPS/ASC proposed rule.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74840 through 74847), we finalized our policy of creating new cost centers and distinct CCRs for implantable devices, magnetic resonance imaging (MRIs), computed tomography (CT) scans, and cardiac catheterization. However, in response to comments we received from our CY 2014 OPPS/ASC proposed rule, we finalized a policy in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74847) to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CCRs used to estimate costs associated with the APCs for CT and MRI. As finalized in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61152), beginning in CY 2021, we use all claims with valid CT and MRI cost center CCRs, including those that use a ''square feet'' cost allocation method, to estimate costs for the CT and MRI APCs.

Comment: One commenter stated that coronary CT angiography (CCTA) requires considerably more resources than the procedures that are currently assigned to the CT cost center. The commenter suggests that this has resulted in over a decade of inadequate reimbursement for CCTA below the actual cost of performing the test. The commenter recommends that CMS provide specific instructions that allow hospitals to submit charges for cardiac CT using revenue codes that provide more accurate cost estimates. The commenter stated that hospitals do not have the ability to directly report costs for cardiac CT services and that CMS regulations mandate that cardiac CT be lumped into generic diagnostic CT revenue codes.

Response: Hospital outpatient facilities make the final determination for reporting the appropriate cost centers and revenue codes. As stated in section 20.5 in Chapter 4 (Part B Hospital) of the Medicare Claims Processing Manual, CMS ''does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under OPPS since hospitals' assignment of cost vary. Where explicit instructions are not provided, providers should report their charges under the revenue code that will result in the charge being assigned to the same cost center to which the cost of those services are assigned in the cost report.'' Therefore, HOPDs must determine the most appropriate cost center and revenue code for the cardiac CT exams.

After consideration of the public comment we received on the general CCR process, we are finalizing for CY 2022 using the hospital-specific overall ancillary and departmental CCRs to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk and the established methodology.

2. Final Data Development and Calculation of Costs Used for Ratesetting

In this section of this final rule with comment period, we discuss the use of claims to calculate the OPPS payment rates for CY 2022. The Hospital OPPS page on the CMS website on which the CY 2022 OPPS/ASC final rule with comment period is posted (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, later in this section we discuss the file of claims that comprises the data set that is available upon payment of an administrative fee under a CMS data use agreement. The CMS website, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html,* includes information about obtaining the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–10–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2019 claims that were used to calculate the final payment rates for the CY 2022 OPPS/ASC final rule with comment period.

Previously, the OPPS established the scaled relative weights on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost.

We did not receive any public comments on our proposed process and are finalizing our proposed methodology to continue to use geometric mean costs to calculate the relative weights on which the final CY 2022 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of this final rule with comment period to calculate the costs we used to establish the final relative payment weights used in calculating the OPPS payment rates for CY 2022 shown in Addenda A and B to the CY 2022 OPPS/ASC final rule with comment period (which are available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*). We refer readers to section II.A.4. of this final rule with comment period for a discussion of the

conversion of APC costs to scaled payment weights.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier ''PN'', which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier ''PN'' from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2022 OPPS, we will continue to remove claim lines with modifier ''PN'' from the ratesetting process.

For details of the claims accounting process used in the CY 2022 OPPS/ASC final rule with comment period, we refer readers to the claims accounting narrative under supporting documentation for the CY 2022 OPPS/ASC final rule with comment period on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

a. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

We proposed to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, to address the differences in CCRs and to better reflect hospitals' costs, we proposed to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We also proposed to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports to simulate blood-specific CCRs for those hospitals. We proposed to calculate the costs upon which the proposed CY 2022 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated blood-specific, CCR methodology better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to believe that using this methodology in CY 2022 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that we defined a comprehensive APC (C–APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C–APCs. We proposed to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C–APCs. Because the costs of blood and blood products would be reflected in the overall costs of the C–APCs (and, as a result, in the proposed payment rates of the C–APCs), we proposed not to make separate payments for blood and blood products when they appear on the same claims as services assigned to the C–APCs (we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795 through 66796) for more information about our policy not to make separate payments for blood and blood products when they appear on the same claims as services assigned to a C–APC).

We refer readers to Addendum B to the CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website) for the proposed CY 2022 payment rates for blood and blood products (which are generally identified with status indicator ''R''). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

For CY 2022, we proposed to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology. We did not receive any comments on our proposal to establish payment rates for blood and blood products using our blood-specific CCR methodology and we are finalizing this policy as proposed. Please refer to Addendum B to the CY 2022 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website) for the final CY 2022 payment rates for blood and blood products.

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per

source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2022, except where otherwise indicated, we proposed to use the costs derived from CY 2019 claims data to set the proposed CY 2022 payment rates for brachytherapy sources because CY 2019 is the year of data we proposed to use to set the proposed payment rates for most other items and services that would be paid under the CY 2022 OPPS. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and brachytherapy source C2636 (Brachytherapy linear source, non-stranded, palladium-103, per 1 mm), we proposed to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we proposed for other items and services paid under the OPPS, as discussed in section II.A.2. of the CY 2022 OPPS/ASC proposed rule. We also proposed to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We proposed to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per-source basis (as opposed to, for example, a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). We also proposed to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010 by section 142 of Pub. L. 110–275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2022 payment rates for brachytherapy sources are included in Addendum B to the CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website) and identified with status indicator ''U''.

For CY 2018, we assigned status indicator ''U'' (Brachytherapy Sources, Paid under OPPS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at $4.69 per mm^2. For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2. Our CY 2018 claims data available for the CY 2020 OPPS/ASC final rule with comment period included two claims with a geometric mean cost for HCPCS code C2645 of $1.02 per mm^2. In response to comments from stakeholders, we agreed with commenters that given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of $1.02 per mm^2 may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2020. Similarly, in the absence of sufficient claims data to establish an APC payment rate, in the CY 2021 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2021.

As discussed in Section X.E. of the CY 2022 OPPS/ASC proposed rule, given our concerns with CY 2020 data as a result of the COVID–19 PHE, in general we proposed to use CY 2019 claims data and the data components related to it in establishing the CY 2022 OPPS. Therefore, we proposed to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2022.

We received no public comments and are finalizing our proposal, without modification, to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2022.

Additionally, for CY 2022 and subsequent calendar years, as discussed in Section X.C. of the CY 2022 OPPS/ASC proposed rule, we proposed to establish a Low Volume APC policy for New Technology APCs, clinical APCs, and brachytherapy APCs. For these APCs with fewer than 100 single claims that can be used for ratesetting purposes in the existing claims year, we proposed to use up to four years of claims data to establish a payment rate for each item or service as we currently do for low volume services assigned to New Technology APCs. Further, we proposed to calculate the cost for Low Volume APCs based on the greatest of the arithmetic mean cost, median cost, or geometric mean cost. We proposed to designate 5 brachytherapy APCs as Low Volume APCs for CY 2022 as these APCs met our proposed criteria to be designated as a Low Volume APC. In Section X.C. of this final rule with comment period, we are finalizing our proposal to designate 5 brachytherapy APCs as Low Volume APCs for CY 2022. For more information on the brachytherapy APCs we are designating as Low Volume APCs, see Section X.C. of this final rule with comment period.

We continue to invite stakeholders to submit recommendations for new codes to describe new brachytherapy sources. Such recommendations should be directed via email to *outpatientpps@cms.hhs.gov* or by mail to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

b. Comprehensive APCs (C–APCs) for CY 2022

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861

through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014 but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C–APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C–APC policy (79 FR 66798 through 66810).

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 through 66810). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70332), we finalized 10 additional C–APCs to be paid under the existing C–APC payment policy and added one additional level to both the Orthopedic Surgery and Vascular Procedures clinical families, which increased the total number of C–APCs to 37 for CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79584 through 79585), we finalized another 25 C–APCs for a total of 62 C–APCs. In the CY 2018 OPPS/ASC final rule with comment period, we did not change the total number of C–APCs from 62. In the CY 2019 OPPS/ASC final rule with comment period, we created three new C–APCs, increasing the total number to 65 (83 FR 58844 through 58846). In the CY 2020 OPPS/ASC final rule with comment period, we created two new C–APCs, increasing the total number to 67 C–APCs (84 FR 61158 through 61166). Most recently, in the CY 2021 OPPS/ASC final rule, we created two new C–APCs, increasing the total number to 69 C–APCs (85 FR 85885).

Under our C–APC policy, we designate a service described by a HCPCS code assigned to a C–APC as the primary service when the service is identified by OPPS status indicator ''J1''. When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as ''adjunctive services'') and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

Services excluded from the C–APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801). A list of services excluded from the C–APC policy is included in Addendum J to the CY 2022 OPPS/ASC final rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*).

In the interim final rule with request for comments (IFC) titled, ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', published on November 6, 2020, we stated that, effective for services furnished on or after the effective date of the IFC and until the end of the PHE for COVID–19, there is an exception to the OPPS C–APC policy to ensure separate payment for new COVID–19 treatments that meet certain criteria (85 FR 71158 through 71160). Under this exception, any new COVID–19 treatment that meets the following two criteria will, for the remainder of the PHE for COVID–19, always be separately paid and will not be packaged into a C–APC when it is provided on the same claim as the primary C–APC service. First, the treatment must be a drug or biological product (which could include a blood product) authorized to treat COVID–19, as indicated in section ''I. Criteria for Issuance of Authorization'' of the FDA letter of authorization for the emergency use of the drug or biological product, or the drug or biological product must be approved by FDA for treating COVID–19. Second, the emergency use authorization (EUA) for the drug or biological product (which could include a blood product) must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or the product must be approved by FDA to treat COVID–19 disease and not limit its use to the inpatient setting. For further information regarding the exception to the C–APC policy for COVID–19 treatments, please refer to the November 6, 2020 IFC (85 FR 71158 through 71160).

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period for the C–APCs and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C–APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator ''J1'', excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator ''J1'' are assigned to C–APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C–APC payment methodology to qualifying extended assessment and management encounters through the ''Comprehensive Observation Services'' C–APC (C–APC 8011). Services within this APC are assigned status indicator ''J2''. Specifically, we make a payment through C–APC 8011 for a claim that:

- Does not contain a procedure described by a HCPCS code to which we have assigned status indicator ''T'';
- Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);
- Contains services provided on the same date of service or one day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379

(Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and

- Does not contain services described by a HCPCS code to which we have assigned status indicator ''J1''.

The assignment of status indicator ''J2'' to a specific set of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C–APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) for further instructions on reporting these services in the context of a C–APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868 through 74869 and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator ''J1'' as a single ''J1'' unit procedure claim (78 FR 74871 and 79 FR 66801). Line item charges for services included on the C–APC claim are converted to line item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator ''J1'' and later used to develop the geometric mean costs for the C–APC relative payment weights. (We note that we use the term ''comprehensive'' to describe the geometric mean cost of a claim reporting ''J1'' service(s) or the geometric mean cost of a C–APC, inclusive of all of the items and services included in the C–APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C–APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator ''J1'' according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator ''J1'' or units thereof, we identify one ''J1'' service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple ''J1'' procedure claims to the C–APC to which the service designated as the primary service is assigned. If the reported ''J1'' services on a claim map to different C–APCs, we designate the ''J1'' service assigned to the C–APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple ''J1'' services on a claim map to the same C–APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator ''J1'' to the most appropriate C–APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and certain add-on codes (as described further below) from the originating C–

APC (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule, as stated in section 1833(t)(2) of the Act and section III.B.2. of this final rule with comment period, in the originating C–APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator ''J1'' (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C–APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of ''J1'' services (or combinations of ''J1'' services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C–APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C–APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary ''J1'' service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2022, we proposed to apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator ''J1'' and any number of units of a single add-on code for the primary ''J1'' service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C–APC within the same clinical family of C–APCs. As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the ''J1'' primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and is not reassigned to the next higher cost C–APC. We list the complexity adjustments for ''J1'' and add-on code combinations for CY 2022, along with all of the other final complexity adjustments, in Addendum J to the CY 2022 OPPS/ASC final rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*).

Addendum J to the CY 2022 OPPS/ASC final rule includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to the CY 2022 OPPS/ASC final rule also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and are finalized to be reassigned to the next higher cost C–APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the first four digits of the designated primary service followed by a letter. For example, the proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C–APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that are proposed to be reassigned to C–APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to the CY 2022 OPPS/ASC proposed rule allows stakeholders the opportunity to better assess the impact associated with the proposed assignment of claims with each of the paired code combinations eligible for a complexity adjustment.

Comment: One commenter expressed support of CMS' proposal to maintain existing complexity adjustment code pairs that were in effect for 2021 and to create new complexity adjustments for certain code pairs for CY 2022.

Response: We thank the commenter for their support.

Comment: Several commenters requested that CMS modify or eliminate the established C–APC complexity adjustment eligibility criteria of 25 or more claims reporting the code combination (frequency) and a violation of the 2 times rule in the originating C–APC (cost) to allow additional code combinations to qualify for complexity adjustments. These commenters expressed concern that CMS' methodology for determining complexity adjustments is unnecessarily restrictive, specifically the 25-claim threshold. One commenter also requested that CMS apply the complexity adjustment to all blue light cystoscopy procedures performed with Cysview ®in the HOPD. The specific C–APC complexity adjustments requested by the commenters are listed in Table 1 below.

Several commenters reiterated their request to allow clusters of procedures, consisting of a ''J1'' code-pair and multiple other associated add-on codes used in combination with that ''J1''

code-pair to qualify for complexity adjustments, stating that this may allow for more accurate reflection of medical practice when multiple procedures are performed together or there are certain complex procedures that include numerous add-on codes. Commenters also requested that CMS continue to monitor and report on the impact of applying complexity criteria on APC assignments for code combinations within C–APCs.

BILLING CODE 4120–01–P

TABLE 1: C-APC Complexity Adjustments Requested by the Commenters

Primary "J1" HCPCS code	Secondary "J1" HCPCS code	Primary C-APC assignment	Requested complexity adjusted C-APC assignment
28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method)	**20900** (Bone graft, any donor area; minor or small (e.g., dowel or button))	5114	5115
28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint)	**28270** (Capsulotomy; metatarsophalangeal joint, with or without tenorrhaphy, each joint (separate procedure))	5114	5115
52214 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands)	**C9738** (Adjunctive blue light cystoscopy with fluorescent imaging agent (list separately in addition to code for primary procedure))	5374	5375
52224 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) or treatment of minor (less than 0.5 cm) lesion(s) with or without biopsy)	**C9738** (Adjunctive blue light cystoscopy with fluorescent imaging agent (list separately in addition to code for primary procedure))	5374	5375

BILLING CODE 4120–01–C

Response: We appreciate these comments. We note that we did not propose that claims with the code combinations suggested by commenters would receive complexity adjustments because they failed to meet either the cost or frequency criteria. We also note that, at this time, we do not believe changes to the C–APC complexity adjustment criteria are necessary or that we should make exceptions to the criteria to allow claims with the code combinations suggested by the commenters to receive complexity adjustments. As we stated in the CY 2017 OPPS/ASC final rule (81 FR 79582), we believe that the complexity adjustment criteria, which require a frequency of 25 or more claims reporting a code combination and a violation of the 2 times rule in the originating C–APC, are appropriate to determine if a combination of procedures represents a complex, costly subset of the primary service that should qualify for the adjustment and be paid at the next higher paying C–APC in the clinical family. If a code combination meets these criteria, the combination receives payment at the next higher cost C–APC. Code combinations that do not meet these

criteria receive the C–APC payment rate associated with the primary ''J1'' service. As we previously stated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61161), a minimum of 25 claims is already a very low threshold for a national payment system. Lowering the minimum of 25 claims further could lead to unnecessary complexity adjustments for service combinations that are rarely performed.

As stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58843), we do not believe that it is necessary to adjust the complexity adjustment criteria to allow claims that include more than two ''J1'' procedures or procedures that are not assigned to C–APCs to qualify for a complexity adjustment. As previously mentioned, we believe the current criteria are adequate to determine if a combination of procedures represents a complex, costly subset of the primary service. We will continue to monitor the application of the complexity adjustment criteria.

After consideration of the public comments we received on the proposed complexity adjustment policy, we are finalizing the C–APC complexity adjustment policy for CY 2022 as proposed. We are also finalizing the complexity adjustments proposed without modification.

(2) Exclusion of Procedures Assigned to New Technology APCs from the C–APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for the procedures. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than two years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than two years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C–APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPPS status indicator ''J1'', payment for the new technology service was typically packaged into the payment for the primary procedure. Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

To address this issue and ensure that there are sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), we finalized excluding payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a ''J1'' service assigned to a C–APC. In the CY 2020 OPPS/ASC final rule with comment period, we finalized that payment for services assigned to a New Technology APC would be excluded from being packaged into the payment for comprehensive observation services assigned status indicator ''J2'' when they are included on a claim with a ''J2'' service starting in CY 2020 (84 FR 61167). We proposed to continue to exclude payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a ''J1'' or ''J2'' service assigned to a C–APC.

We did not receive any comments on this policy. We are finalizing as proposed without modification to continue this exclusion policy.

(3) Additional C–APCs for CY 2022

In the CY 2022 proposed rule, we proposed to continue to apply the C–APC payment policy methodology. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C–APC payment policy methodology and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, we did not propose to convert any standard APCs to C–APCs in CY 2022, thus we proposed that the number of C–APCs for CY 2022 would be the same as the number for CY 2021, which is 69 C–APCs.

Comment: One commenter requested that CMS designate APC 5372 (Level 2 Urology and Related Services) as a Comprehensive APC, noting that all other Urology and Related Services APCs are C–APCs and multiple procedures within this APC would qualify for complexity adjustments.

Response: We appreciate the commenter's suggestion and will consider it for future rulemaking.

Comment: Several commenters requested that CMS discontinue the C–APC payment policy for all surgical insertion codes required for brachytherapy treatment. The commenters were concerned that the C–APC methodology lacks the charge capture mechanisms to accurately reflect the cost of radiation oncology services, particularly the delivery of brachytherapy for the treatment of cervical cancer. They also stated that they oppose C–APC payment for cancer care given the complexity of coding, use of serial billing, and the potential for different sites of service for the initial surgical device insertion and subsequent treatment delivery or other supportive services. These commenters suggested that CMS assign brachytherapy procedures to traditional APCs, move brachytherapy procedures to higher paying C–APC, or pay separately for preparation and planning services to fully account for the costs associated with these procedures.

Response: We appreciate the comments. The calculations provided by commenters as to the cost of these services do not match how we calculate C–APC costs. We believe that the current C–APC methodology is appropriately applied to these surgical procedures and is accurately capturing costs. We will continue to examine these concerns and will determine if any modifications to this policy are warranted in future rulemaking.

After consideration of the public comments we received, we are finalizing our C–APC policy and the proposed C–APCs as proposed for CY 2022. Table 2 below lists the final C–APCs for CY 2022, all of which were established in past rules. All C–APCs are displayed in Addendum J to this CY 2022 OPPS/ASC final rule with comment period (which is available via the internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*). Addendum J to this final rule with comment period also contains all of the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information for CY 2022.

BILLING CODE 4120–01–P

TABLE 2: Final CY 2022 C-APCs

C-APC	CY 2022 APC Group Title	Clinical Family	New C-APC
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX	
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX	
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5112	Level 2 Musculoskeletal Procedures	ORTHO	
5113	Level 3 Musculoskeletal Procedures	ORTHO	
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	
5154	Level 4 Airway Endoscopy	AENDO	
5155	Level 5 Airway Endoscopy	AENDO	
5163	Level 3 ENT Procedures	ENTXX	
5164	Level 4 ENT Procedures	ENTXX	
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5182	Level 2 Vascular Procedures	VASCX	
5183	Level 3 Vascular Procedures	VASCX	
5184	Level 4 Vascular Procedures	VASCX	
5191	Level 1 Endovascular Procedures	EVASC	
5192	Level 2 Endovascular Procedures	EVASC	
5193	Level 3 Endovascular Procedures	EVASC	
5194	Level 4 Endovascular Procedures	EVASC	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	
5302	Level 2 Upper GI Procedures	GIXXX	
5303	Level 3 Upper GI Procedures	GIXXX	
5313	Level 3 Lower GI Procedures	GIXXX	
5331	Complex GI Procedures	GIXXX	
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5361	Level 1 Laparoscopy and Related Services	LAPXX	
5362	Level 2 Laparoscopy and Related Services	LAPXX	
5373	Level 3 Urology and Related Services	UROXX	
5374	Level 4 Urology and Related Services	UROXX	
5375	Level 5 Urology and Related Services	UROXX	

C-APC	CY 2022 APC Group Title	Clinical Family	New C-APC
5376	Level 6 Urology and Related Services	UROXX	
5377	Level 7 Urology and Related Services	UROXX	
5378	Level 8 Urology and Related Services	UROXX	
5414	Level 4 Gynecologic Procedures	GYNXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	
5432	Level 2 Nerve Procedures	NERVE	
5461	Level 1 Neurostimulator and Related Procedures	NSTIM	
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5465	Level 5 Neurostimulator and Related Procedures	NSTIM	
5471	Implantation of Drug Infusion Device	PUMPS	
5491	Level 1 Intraocular Procedures	INEYE	
5492	Level 2 Intraocular Procedures	INEYE	
5493	Level 3 Intraocular Procedures	INEYE	
5494	Level 4 Intraocular Procedures	INEYE	
5495	Level 5 Intraocular Procedures	INEYE	
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	
8011	Comprehensive Observation Services	N/A	

C-APC Clinical Family Descriptor Key:

AENDO = Airway Endoscopy
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
BREAS = Breast Surgery
COCHL = Cochlear Implant
EBIDX = Excision/ Biopsy/Incision and Drainage
ENTXX = ENT Procedures
EPHYS = Cardiac Electrophysiology
EVASC = Endovascular Procedures
EXEYE = Extraocular Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
GYNXX = Gynecologic Procedures
INEYE = Intraocular Surgery
LAPXX = Laparoscopic Procedures
NERVE = Nerve Procedures
NSTIM = Neurostimulators
ORTHO = Orthopedic Surgery
PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
SCTXX = Stem Cell Transplant
UROXX = Urologic Procedures
VASCX = Vascular Procedures
WPMXX = Wireless PA Pressure Monitor

c. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. (We note that, in the CY 2018 OPPS/ASC final rule with comment period, we finalized a policy to delete the composite APC 8001 (LDR Prostate Brachytherapy Composite) for CY 2018 and subsequent years.) We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241 through 59242 and 59246 through 52950) for more recent background.

(1) Mental Health Services Composite APC

We proposed to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79588 through 79589), we finalized a policy to combine the existing Level 1 and Level 2 hospital-based PHP APCs into a single hospital-based PHP APC, and thereby discontinue APCs 5861 (Level 1—Partial Hospitalization (3 services) for Hospital-Based PHPs) and 5862 (Level 2—Partial Hospitalization (4 or more services) for Hospital-Based PHPs) and replace them with APC 5863 (Partial Hospitalization (3 or more services per day)).

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580 through 33581 and 59246 through 59247, respectively), we proposed and finalized the policy for CY 2018 and subsequent years that, when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 (Mental Health Services Composite). In addition, we set the payment rate for composite APC 8010 for CY 2018 at the same payment rate that will be paid for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital will continue to be paid the payment rate for composite APC 8010. Under this policy, the I/OCE will continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5863 for all of the specified mental health services furnished by the hospital on that single date of service. We continue to believe that the costs associated with administering a partial hospitalization program at a hospital represent the most resource intensive of all outpatient mental health services. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

We proposed that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2022. In addition, we proposed to set the payment rate for composite APC 8010 at the same payment rate that we proposed for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid the proposed payment rate for composite APC 8010.

We did not receive any public comment on these proposals and are finalizing them as proposed. In particular, we are finalizing our proposal, without modification, that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2022. In addition, we are finalizing our proposal to set the payment rate for composite APC 8010 for CY 2022 at the same payment rate that we set for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) Ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 3 below.

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be

provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the ''with contrast'' composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the ''with contrast'' composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2022, we proposed to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

For CY 2022, except where otherwise indicated, we proposed to use the costs derived from CY 2019 claims data to set the proposed CY 2022 payment rates. Therefore, for CY 2022, the payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) are based on proposed geometric mean costs calculated from CY 2019 claims available for the CY 2022 OPPS/ASC proposed rule that qualified for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we have used to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to the CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website[1]) and are discussed in more detail in section II.A.1.b. of the CY 2022 OPPS/ASC proposed rule (86 FR 42034 through 42040).

For the CY 2022 OPPS/ASC proposed rule, we were able to identify approximately 1.04 million ''single session'' claims out of an estimated 2.2 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 47 percent of all eligible claims, to calculate the proposed CY 2022 geometric mean costs for the multiple imaging composite APCs. Table 2 of the CY 2022 OPPS/ASC proposed rule lists the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2022 (86 FR 42037 through 42040).

We did not receive any public comments on these proposals. We are finalizing our proposal to continue the use of multiple imaging composite APCs to pay for services providing more than one imaging procedure from the same family on the same date, without modification. Table 3 below lists the HCPCS codes that will be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC final geometric mean costs for CY 2022.

BILLING CODE 4120–01–P

[1] CY 2022 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS–1753–P); Notice of Proposed Rulemaking. Available at: *https://www.cms.gov/medicaremedicare-fee-service-paymenthospital outpatientppshospital-outpatient-regulations-and-notices/cms-1753-p.*

TABLE 3: OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2022 APC 8004 (Ultrasound Composite)	**CY 2022 Approximate APC Geometric Mean Cost = $290.66**
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2022 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2022 Approximate APC Geometric Mean Cost = $218.54**
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2022 APC 8006 (CT and CTA with Contrast Composite)	**CY 2022 Approximate APC Geometric Mean Cost = $424.16**
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+

70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* If a "without contrast" CT or CTA procedure is performed during the same session as a "with contrast" CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	

CY 2022 APC 8007 (MRI and MRA without Contrast Composite)*	CY 2022 Approximate APC Geometric Mean Cost = $509.37
0609T	Mrs disc pain acquisj data
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2022 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2022 Approximate APC Geometric Mean Cost = $821.63**
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye

70549	Mr angiograph neck w/o & w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal

C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a "without contrast" MRI or MRA procedure is performed during the same session as a "with contrast" MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.	

BILLING CODE 4120–01–C

3. Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. For an extensive discussion of the history and background of the OPPS packaging policy, we refer readers to the CY 2000 OPPS final rule with comment period (65 FR 18434), the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70343), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79592), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59250), the CY 2019 OPPS/ASC final rule with comment period (83 FR 58854), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 85894). As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

For CY 2022, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and hospital outpatient department billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies.

For CY 2022, we proposed no changes to the overall packaging policy previously discussed. We proposed to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code. Below we discuss a proposed change to an ASC payment system packaging policy for CY 2022 and solicit comment on potential additional changes to that policy and application of that policy to the OPPS.

We did not receive any public comments on the overall OPPS packaging policy and are finalizing our packaging policy as proposed. Specific packaging concerns are discussed in detail in their respective sections throughout this final rule with comment period.

b. ASC Payment System Policy for Non-Opioid Pain Management Drugs and Biologicals That Function as Surgical Supplies

(1) Background on OPPS/ASC Non-Opioid Pain Management Packaging Policies

In the CY 2018 OPPS/ASC proposed rule (82 FR 33588), within the framework of existing packaging categories, such as drugs that function as supplies in a surgical procedure or diagnostic test or procedure, we requested stakeholder feedback on common clinical scenarios involving currently packaged items and services described by HCPCS codes that stakeholders believe should not be packaged under the OPPS. We also expressed interest in stakeholder feedback on common clinical scenarios

involving separately payable HCPCS codes for which payment would be most appropriately packaged under the OPPS. Commenters who responded to the CY 2018 OPPS/ASC proposed rule expressed a variety of views on packaging under the OPPS. While several commenters supported maintaining packaging policies, most of the public comments ranged from requests to unpackage most items and services that are unconditionally packaged under the OPPS, including drugs and devices, to specific requests for separate payment for a particular drug or device.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52485), we reiterated our position with regard to payment for Exparel®, a non-opioid analgesic that functions as a surgical supply, stating that we believed that payment for this drug is appropriately packaged with the primary surgical procedure. We also stated in the CY 2018 OPPS/ASC final rule with comment period that we would continue to explore and evaluate packaging policies under the OPPS and consider these policies in future rulemaking.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58855), we explained that, in addition to stakeholder feedback regarding OPPS packaging policies, the President's Commission on Combating Drug Addiction and the Opioid Crisis (the Commission) [2] had recently recommended that CMS examine payment policies for certain drugs that function as a supply, specifically non-opioid pain management treatments. The Commission was established in 2017 to study the scope and effectiveness of the Federal response to drug addiction and the opioid crisis and to make recommendations to the President for improving the Federal response to the crisis. The Commission's report included a recommendation for CMS to '' . . . review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain. . . .'' We explained that, as discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37068 through 37071), in response to stakeholder comments on the CY 2018 OPPS/ASC proposed rule and in light of the recommendations regarding payment policies for certain drugs, we had recently evaluated the impact of our packaging policy for drugs that function as a supply when used in a surgical procedure on the utilization of these drugs in both the hospital outpatient department and the ASC setting. We stated that, although we found increases in utilization of Exparel when it was paid under the OPPS, we noticed decreased utilization of Exparel under the ASC payment system. Accordingly, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58855 through 58860), we finalized a policy to unpackage and pay separately at ASP+6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019, due to decreased utilization in the ASC setting. Historically, we stated that we consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy (79 FR 66875).

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT) Act (Pub. L. 115–271) was enacted. Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. As part of this review, under section 1833(t)(22)(A)(iii) of the Act, the Secretary must consider the extent to which revisions to such payments (such as the creation of additional groups of covered outpatient department (OPD) services to separately classify those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce the payment incentives for using opioids instead of non-opioid alternatives for pain management. In conducting this review and considering any revisions, the Secretary must focus on covered OPD services (or groups of services) assigned to C–APCs, APCs that include surgical services, or services determined by the Secretary that generally involve treatment for pain management. If the Secretary identifies revisions to payments pursuant to section 1833(t)(22)(A)(iii) of the Act, section 1833(t)(22)(C) of the Act requires the Secretary to, as determined appropriate, begin making revisions for services furnished on or after January 1, 2020. Revisions under this paragraph are required to be treated as adjustments for purposes of paragraph (9)(B) of the Act, which requires any adjustments to be made in a budget neutral manner. Section 1833(i)(8) of the Act, as added by section 6082(b) of the SUPPORT Act, requires the Secretary to conduct a similar type of review as required for the OPPS and to make revisions to the ASC payment system in an appropriate manner, as determined by the Secretary.

For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), as required by section 1833(t)(22)(A)(i) of the Act, we reviewed payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. We used currently available data to analyze the payment and utilization patterns associated with specific non-opioid alternatives, including drugs that function as a supply, nerve blocks, and neuromodulation products, to determine whether our packaging policies may have reduced the use of non-opioid alternatives. For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), we proposed to continue our policy to pay separately at ASP+6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2020. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173 through 61180), after reviewing data from stakeholders and Medicare claims data, we did not find compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP+6 percent for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this

[2] *https://www.federalregister.gov/documents/2017/04/03/2017-06716/establishing-the-presidents-commission-on-combating-drug-addiction-and-the-opioid-crisis.*

policy, for CY 2020, the only drug that qualified for separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply was Exparel.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85896 to 85899), we continued the policy to pay separately at ASP+6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021. For CY 2021, only two drug products met the criteria as non-opioid pain management drugs that function as surgical supplies in the ASC setting, and thus receive separate payment under the ASC payment system. These drugs are Exparel and Omidria.

(2) CY 2022 Evaluation of Payments for Opioids and Non-Opioid Alternatives for Pain Management and Comment Solicitation on Extending the Policy to the OPPS

As noted in the background above, over the past several years we have reviewed non-opioid alternatives and evaluated the impact of our packaging policies on access to these products. In our previous evaluations, we used currently available data to analyze the payment and utilization patterns associated with specific non-opioid alternatives, including drugs that function as a supply, nerve blocks, and neuromodulation products, to determine whether our packaging policies may have reduced the use of non-opioid alternatives. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85896 through 85899), we stated that we would continue to analyze the issue of access to non-opioid pain management alternatives in the HOPD and the ASC settings as part of any reviews we conduct under section 1833(t)(22)(A)(ii) of the Act, with a specific focus on whether there is evidence that our current payment policies are creating access barriers for other non-opioid pain management alternatives for which there is evidence-based support that these products help to deter or avoid prescription opioid use and opioid use disorder.

For CY 2022, we conducted a subsequent review of payments for opioids and non-opioid alternatives as authorized by section 1833(t)(22)(A)(ii) of the Act. We analyzed utilization patterns in both the HOPD and ASC settings for multiple non-opioid pain management drugs, including the two drugs that are receiving separate payment when furnished in the ASC setting under our current policy for CY 2021: Exparel and Omidria. The results of our CY 2022 review were similar to the results of our reviews in previous years. Generally, utilization of non-opioid pain management drugs continued to increase year after year in the HOPD setting, where payment for these non-opioid alternatives is packaged with the payment for the associated surgical procedure. In the ASC setting, where Exparel and Omidria are separately paid, we also saw utilization increases for these two drugs. However, in the ASC setting, the rate of increase in utilization is much more substantial than in the HOPD setting. In particular, in the HOPD setting where payment for Exparel is packaged, utilization of Exparel increased from 19.7 million units in 2019 to 21.8 million units in 2020, whereas utilization of Exparel increased from 1.5 million units in 2019 to 3.3 million units in 2020 in the ASC setting, where Exparel is separately paid. We note that a number of reasons could explain this discrepancy other than our policy to pay separately for Exparel under the ASC payment system, including evolving clinical practice in the ASC setting, which could increase the number of surgeries performed in ASCs for which Exparel is an appropriate pain management drug.

We have consistently explained, including as recently as in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85894), that our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item. We have not found conclusive evidence to support the notion that the OPPS packaging policy, under which non-opioid drugs and biologicals are packaged when they function as a supply in a surgical procedure, has created financial incentives to use opioids instead of evidence-based non-opioid alternatives for pain management. For example, we have not observed decreased utilization of non-opioid alternatives for pain management in the HOPD setting. Therefore, for CY 2022, we proposed to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting.

As explained earlier in this section, while packaging encourages efficiency and is a fundamental component of a prospective payment system, where there is an overriding policy objective to reduce disincentives for use of non-opioid products to the extent possible, we believe it may be appropriate to establish payment that reduces disincentives for use of non-opioid drugs and biologicals for pain management when there is evidence that use of those products reduces unnecessary opioid use. For these reasons, we solicited comment as to whether we should expand our current policy that only applies in the ASC setting—to pay separately at ASP+6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting—to the HOPD setting.

In the CY 2022 OPPS/ASC proposed rule, we stated we were interested in learning from stakeholders whether similar disincentives for the use of non-opioid pain management drugs and biologicals identified in the ASC setting exist in the HOPD setting. Previously, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59067), we identified several disincentives that were unique to the ASC setting compared to the HOPD setting, including the fact that ASCs tend to provide specialized care and a more limited range of services in comparison to hospital outpatient departments. Also, ASCs are paid, in aggregate, approximately 55 percent of the OPPS rate. Therefore, fluctuations in payment rates for specific services may affect these providers more acutely than hospital outpatient departments; and ASCs may be less likely to choose to furnish non-opioid postsurgical pain management treatments, which are typically more expensive than opioids, as a result. Additionally, we sought comment on what evidence supports the expansion of this policy to the HOPD setting, including the clinical benefit that Medicare beneficiaries may receive from the availability of separate or modified payment for these products in the HOPD setting.

Finally, in the proposed rule we sought comment on if we should treat

products the same depending on the setting, ASC or HOPD. For example, we sought comment on whether products should have the same eligibility requirements to qualify for revised payment in the ASC and the HOPD settings. We also sought comment on how the additional comment solicitations described below, which refer to the ASC setting, could also be applied to the HOPD setting.

Comment: MedPAC commented that while it appreciated CMS's interest in addressing the issue of opioid overuse it continued to support a policy that maintains the packaging of drugs that function as supplies in surgical procedures. MedPAC stated that this policy is contrary to CMS's efforts to increase the size of payment bundles in the OPPS to increase incentives for efficient delivery of care.

Response: We appreciate this feedback. We agree that packaging policies are a fundamental component of the OPPS and ASC payment systems. We strive to balance the importance of our packaging policies with the importance of addressing the opioid epidemic. In this specific scenario, we believe separate payment in the ASC setting for non-opioid pain management drugs and biologicals that function as surgical supplies is appropriate given the financial disincentives we have observed for these products in the ASC setting. As previously discussed, we identified several disincentives that were unique to the ASC setting compared to the HOPD setting, including the fact that ASCs tend to provide specialized care and a more limited range of services in comparison to hospital outpatient departments.

Comment: Most commenters were in favor of expanding the policy to provide separate payment under the ASC payment system for certain non-opioid pain management drugs that function as surgical supplies to the HOPD setting. Many providers commented that non-opioid pain management therapies are often superior to opioid-based ones in reducing pain, and indicated that they generally would prefer to use non-opioid therapies. However, many stated that payment dictated whether they could use a specific therapy. As such, commenters stated that the pain management therapies available in the ASC setting are not used to the same degree as in the HOPD setting. Commenters stated that although there has not been a drastic decrease in HOPD utilization of non-opioid pain management drugs, the utilization of opioid alternatives could be much higher if separate payment for these products was provided. Similarly, several commenters acknowledged that the disincentives to provide non-opioid pain management drugs in the HOPD setting were not as substantial as the ASC setting; however, according to these stakeholders, there are still financial disincentives to use opioids instead of opioid alternatives in the HOPD setting. A drug manufacturer discussed its view on the disparities in utilization and access to non-opioid pain management therapies in the HOPD setting compared to the ASC setting. Based on this commenter's geo-sociodemographic analysis, they believe that ASC access to their drug outpaced access in the HOPD setting due to CMS payment policies. A few drug manufacturers provided specific data on utilization of their individual products. Omeros, the manufacturer of the drug Omidria, cited that the drug's utilization had, in their view, decreased in the HOPD setting as a result of CMS packaging polices. Many commenters suggested that opioids were more cost effective for their HOPD facilities to use compared to non-opioid pain management drugs due to CMS payment policies. Some commenters suggested that a greater number of surgeries, particularly those with higher acuity and complexity that require pain management drugs, occur in the HOPD setting, compared to the ASC setting. The commenters contended that separate payment for non-opioid pain management drugs in this setting could potentially increase access to these treatments. Therefore, the commenters encouraged CMS to expand this policy to the HOPD setting.

The commenters generally encouraged payment parity across the ASC and HOPD settings in order to enhance site neutrality and prevent a diversion of patients to the ASC setting based solely on the availability of separate payment for non-opioid pain management drugs. MedPAC had concerns that our proposed policy would further distort payment differences between two care settings that are the sites of many of the same services, creating financial incentives for providers to direct patients to one setting of care. Many commenters and providers pointed to the clinical benefit of non-opioid treatments, and encouraged CMS to pay separately, incentivize, or otherwise recognize the value of these drugs in the HOPD setting, regardless of utilization patterns. Commenters provided literature supporting the benefits of non-opioid pain management approaches, including how certain non-opioid pain management products were effective for pain and reduced opioid consumption.

Response: We appreciate the many detailed comments we received from a wide variety of stakeholders in response to our comment solicitation on expanding our non-opioid pain management payment policy to the HOPD setting as well as those regarding the clinical benefit of non-opioid pain management treatments used in their clinical practice.

As discussed in the CY 2022 OPPS/ASC proposed rule, we did not make a proposal to expand this policy to the HOPD setting based on many factors, including our continued claims analysis that demonstrates increasing utilization year after year of these products in the HOPD setting. In the proposed rule, we described our claims analysis for Exparel, a drug for which we have more than five years of reliable claims data. As stated in the proposed rule, even while Exparel was packaged in the HOPD setting, claims data shows that utilization continued to steadily increase year over year. For other drugs described by stakeholders, we found similar increases over years of claims data. We will continue to track the utilization in the HOPD and ASC settings for all of these drugs. However, as Exparel is the only drug that has been not recently been on pass-through and has been packaged in the HOPD setting over the last three years, we believe that Exparel's utilization is a good indicator of whether our payment policies are causing disincentives for non-opioids in the HOPD setting. We have explained in several prior rulemakings, including in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85894), that our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. As previously discussed, we strive to balance the importance of our packaging policies with the importance of addressing the opioid epidemic. In this specific scenario, we believe separate payment in the ASC setting for non-opioid pain management drugs and biologicals that function as surgical supplies is appropriate, given the financial disincentives we have observed for these products in the ASC setting. We identified several disincentives that were unique to the ASC setting compared to the HOPD setting, including the fact that ASCs tend to provide specialized care and a more limited range of services in comparison to hospital outpatient departments. Also, ASCs are paid, in aggregate, approximately 55 percent of the OPPS

rate. Therefore, fluctuations in payment rates for specific services may affect these providers more acutely than hospital outpatient departments; and ASCs may be less likely to choose to furnish non-opioid postsurgical pain management treatments, which are typically more expensive than opioids, as a result. We have not observed the same financial disincentives in the HOPD setting. We have also not observed conclusive trends that our packaging policies for non-opioid pain management are shifting patients from the HOPD setting to the ASC setting.

After reviewing the public comments received, as described previously, we have not found conclusive evidence to support the notion that the OPPS packaging policy, under which non-opioid drugs and biologicals are packaged when they function as a supply in a surgical procedure, has created financial incentives to use opioids instead of evidence-based non-opioid alternatives for pain management. Our goal is to eliminate the disincentive to use non-opioid pain management drugs, rather than to incentivize products in the HOPD setting as some commenters have suggested. At this time, we have not observed any clear and conclusive financial disincentive to use non-opioid pain management drugs over opioids in the HOPD setting. However, based on the comments we received, we will continue to carefully analyze utilization data and engage with stakeholders.

Therefore, for CY 2022, we are finalizing as proposed our proposal to continue to package payment under the OPPS for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the HOPD setting.

(3) Criteria for Eligibility for Separate Payment Under the ASC Payment System for Non-Opioid Pain Management Drugs and Biologicals That Function as Surgical Supplies

As described in section 1833(t)(22)(A)(i) of the Act, the Secretary shall conduct a review of payments for opioids and evidence-based non-opioid alternatives for pain management with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. In any future reviews the Secretary may determine appropriate to conduct under section 1833(t)(22)(A)(ii) of the Act, we believe it is important to establish the evidence base for non-opioid alternatives for pain management when evaluating whether current payment policies result in an incentive for providers to use opioids instead of such evidence-based non-opioid alternatives for pain management.

Accordingly, for CY 2022 and subsequent years, we proposed two criteria that non-opioid pain management drugs and biologicals would be required to meet to be eligible for a payment revision under the ASC payment system in accordance with section 1833(t)(22)(C). The proposed criteria were intended to identify non-opioid pain management drugs and biologicals that function as supplies in surgical procedures for which revised payment under the ASC payment system would be appropriate.

Comment: Most commenters supported continuing our policy of separate payment for non-opioid pain management drugs that function as surgical supplies in the ASC setting. Commenters believe continuing separate payment in the ASC setting is essential given the continued overall low utilization of these drugs in the ASC setting and the positive clinical benefit the drugs provide.

Response: We thank commenters for their support for our proposal. In the following sections we discuss in greater detail the specific aspects of the policy that commenters addressed.

Comment: MedPAC expressed reservations regarding our policy to pay ASCs separately for non-opioid pain management drugs that function as supplies. It stated this policy is contrary to CMS's policy efforts to increase the size of payment bundles in order to increase incentives for efficient delivery of care. Additionally, it stated paying separately in the ASC would distort payment differences between the ASC and HOPD settings. Generally, MedPAC supported a policy that maintains the packaging of drugs that function as supplies in surgical procedures, especially in the absence of evidence in peer-reviewed publications indicating that the drug in question reduces the use of opioids.

Response: We appreciate this comment and agree with the importance of maintaining our overarching packaging policies in the OPPS and ASC payment systems. However, given the seriousness of the opioid epidemic, we continue to believe this policy plays an important role in maintaining beneficiary access and enhancing patient care in the ASC setting by eliminating the financial disincentive to use non-opioid pain management drugs that function as surgical supplies over opioids.

Based on public comments received, for CY 2022, we are finalizing our proposal as proposed to continue our current policy to pay separately for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the ASC setting. We are also finalizing the new additional eligibility criteria we proposed for this policy, as discussed in the following section.

Specifically, for CY 2022, we proposed the following criteria that non-opioid pain management drugs and biologicals that function as surgical supplies would be required to meet to be eligible for separate payment under the ASC payment system in accordance with section 1833(t)(22)(C) of the Act.

Criterion One: FDA Approval and FDA-Approved Indication for Pain Management or Analgesia

We proposed that the drug or biological product must be safe and effective, as determined by FDA. We proposed that the drug must be approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j), or, in the case of a biological product, be licensed under section 351 of the Public Health Service Act (the PHS Act). We further proposed that the drug or biological must also have an FDA-approved indication for pain management or analgesia. We believe FDA approval is an appropriate requirement for a drug or biological to be eligible for this policy because FDA reviews new drugs and biologicals for safety and effectiveness, which would allow us to identify safe and effective non-opioid products to which this separate payment policy would apply. Given that FDA has an existing and detailed review process already in place, we believe it would be appropriate and administratively efficient to utilize FDA approval as a requirement to ensure that the new drugs and biologicals approved under this policy are safe and effective for their intended use. We believe the vast majority of drugs and biologicals on the market have undergone FDA review and approval, and we do not anticipate this criterion would prevent otherwise eligible drugs or biologicals from qualifying. In addition, section 1833(t)(22)(A) of the Act, our current policy, and our proposed policy all focus on pain management products. Specifically, section 1833(t)(22)(A) of the Act refers to reviews of opioid and evidence-based non-opioid products for pain management. Therefore, we proposed to require an FDA-approved indication for pain management or analgesia for a drug or biological to qualify as a pain management product.

The FDA approval process would also allow us to confirm that a drug or biological is, in fact, a non-opioid. Drugs and biologicals that are characterized as opioids or opioid agonists in the labeling for the FDA-approved product would not be eligible for separate payment under this policy.

Comment: Many commenters recommended CMS finalize its proposal to require an FDA-approved indication for pain management or analgesia for a drug or biological to qualify as a pain management product. Numerous commenters believe that this criterion is objective and would provide a transparent requirement for this policy moving forward. Commenters stated that FDA has a thorough and comprehensive process for evaluating drugs for approval and for specific FDA-approved indications. Other commenters did not express outright support for this criterion, but rather said they were not opposed to it. Generally, commenters were in favor of establishing an FDA approval requirement.

Response: We thank commenters for their support. As described in our proposal, we agree with the importance of utilizing FDA approval and an indication for pain management as a criterion for separate payment for eligible non-opioids.

Comment: Some commenters did not support requiring a specific FDA-approved indication for pain management or analgesia because the commenters believed this requirement may limit the number of products to which the policy would apply. One commenter asked us to clarify whether an FDA-approved indication for the treatment of pain would be considered appropriate and satisfy this criterion. One drug manufacturer more generally asked for flexibility in the exact FDA-approved indication. This commenter stated CMS should allow flexibility for a variety of indication statements that demonstrate that a drug mitigates or otherwise alleviates pain. Additionally, this commenter asked CMS to clarify if providing a drug during the pre-operative, post-operative, or intraoperative period could potentially qualify under the proposed policy. Some commenters asked CMS to expand this FDA-approved indication criterion to include anesthesia drugs, drugs used to treat inflammation, or more generally, any drugs that may have pain management properties. An additional commenter suggested limiting eligibility to drugs or biologicals with more restrictive FDA-approved indications, such as those drugs with opioid-sparing pain management indications.

Response: Regarding comments on a specific FDA-approved indication, we believe an FDA-approved indication for pain management or analgesia is appropriate for this policy. Section 1833(t)(22) of the Act required us to assess incentives to use opioids rather than non-opioid products used for pain management. We believe using the FDA-approved indications as a method to determine which drug products are safe and effective for pain management is appropriate. Therefore, we do not believe drugs or biologicals that do not have an FDA—approved indication for pain management or as an analgesic, such as certain anesthesia drugs mentioned by stakeholders, would be appropriate under this policy. We do believe ''treatment of pain'' as described by one commenter, would be an appropriate indication to satisfy this criterion. In response to the recommendation that we include drugs used to treat inflammation, or more generally, any drugs that may have pain management properties, we are not modifying our proposal to include these types of drugs in the definition of an FDA-approved indication for pain management or analgesia.

Additionally, we remind commenters that we consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy (83 FR 58855). Additionally, a drug product must meet all other requirements for payment and coverage under Medicare Part B in order to be paid and covered under this policy. We believe including those drugs with FDA-approved indications for pain management or analgesia will capture the appropriate drug products intended for this policy without being so broad as to include drugs that may not be used for pain management or so restrictive as to exclude potentially useful non-opioid pain management products.

Based on our review of public comments, we are finalizing criterion one as proposed, under which the drug or biological product must be safe and effective, as determined by FDA, and that the drug must be approved under a new drug application under section 505(c) of FDCA, under an abbreviated new drug application under section 505(j), or, in the case of a biological product, be licensed under section 351 of the PHS Act. We are also finalizing for CY 2022 as part of criterion one the requirement that the drug or biological also have an FDA-approved indication for pain management or analgesia.

Criterion Two: Cost of the Product

Currently under the OPPS, drugs that are not policy-packaged are subject to the drug packaging threshold. In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set at $50 per administration during CYs 2005 and 2006. We set the packaging threshold for establishing separate APCs for drugs and biologicals through annual notice and comment rulemaking. The proposed per-day drug packaging threshold for CY 2022 was $130, and the finalized per-day drug packaging threshold for CY 2022 is $130, as described in V.B.1.a of this final rule with comment period.

As our second criterion, we proposed that a drug or biological would only be eligible for a payment revision under the ASC payment system in accordance with section 1833(t)(22)(C) of the Act if its per-day cost exceeds the drug packaging threshold described in section V.B.1.a. of this final rule with comment period. We believe this is an appropriate requirement because we believe that not all non-opioid alternative treatments are equally disincentivized by our packaging policies. In particular, when the cost of non-opioid drugs and biologicals falls below the packaging threshold of $130 per-day, we believe the drug does not generally have a significant impact on the overall procedure costs; therefore, we believe use of these drugs and biologicals is less likely to be disincentivized by CMS packaging policies. However, when the per-day cost of the drug is above the drug packaging threshold, we believe the cost of these drugs or biologicals is more likely to have a significant impact on the overall procedure costs. Section 1833(t)(22)(A)(i) of the Act discusses financial incentives to use opioids instead of non-opioid alternative treatments. As such, we do not believe non-opioid pain management drugs that are lower in cost are generally disincentivized by our packaging policies, as their cost is more easily absorbed into the payment for the primary procedure in which they are used when compared to drugs and biologicals with costs above the threshold. We proposed to use the existing OPPS drug packaging threshold as it is familiar to stakeholders and its application to drugs and biologicals under this policy creates uniformity across the OPPS and ASC payment systems. Therefore, CMS proposed that drugs and biologicals would be required to have a per-day cost that exceeds the drug packaging threshold that CMS sets

annually through notice and comment rulemaking.

We also believe the use of this threshold as an eligibility criterion for drugs under consideration for separate payment under this policy is appropriate, as it conforms with the broader goals of the OPPS and ASC payment systems. Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies, including the drug packaging threshold, support our strategic goal of using larger payment bundles to maximize hospitals' incentives to provide care in the most efficient manner. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. For the reasons mentioned above, we believe it is appropriate to continue to package drugs that would otherwise qualify for separate payment under this policy where their per-day cost is below the OPPS drug packaging threshold.

Comment: Most commenters supported this criterion. Some commenters stated that they agreed with CMS's rationale that use of drugs and biologicals with per-day costs below the packaging threshold is not generally disincentivized by CMS packaging policies. Commenters generally thought this was a clear, transparent, and objective criterion. Other commenters did not express outright support for this criterion but stated that they were not opposed to it.

Response: We thank commenters for their support of this proposed criterion.

Comment: A few commenters stated that non-opioid pain management drugs that fall below the drug packaging threshold are still expensive relative to opioids, and therefore, the commenters believed CMS should not finalize a cost threshold for this policy. Specifically, the manufacturer of Anjeso (HCPCS code J1738; *Injection, meloxicam, 1 mg*), Baudax Bio, supported CMS adopting policies that encourage use of non-opioid pain alternatives. However, they recognized that the per-day cost of their product fell below the drug packaging threshold and disagreed with CMS's proposed criterion two regarding per-day cost, because they indicated that the relative cost of opioids is still less than most non-opioid pain management products. Other commenters recommended that CMS pay for drugs and biologicals with per-day costs that fall below the drug packaging threshold, such as intravenous (IV) acetaminophen.

Response: We thank the commenters for their feedback on this proposed criterion. At this time, we continue to believe that drugs and biologicals with per-day costs below the OPPS drug packaging threshold are not generally disincentivized by CMS packaging policies, as the drug cost is less likely to represent a substantial portion of the payment rate of the primary procedure in which the product is used. This criterion aligns with our policy objective of eliminating financial disincentives to use of non-opioid pain management products.

Based on our rationale described above and feedback from stakeholders, we believe it is appropriate to finalize the second criterion as proposed. For CY 2022, we are finalizing our proposal that a non-opioid pain management drug or biological that functions as a supply in a surgical procedure would only be eligible for separate payment under the ASC payment system if its per-day cost exceeds the drug packaging threshold described in section V.B.1.a. of this final rule with comment period.

In addition, we proposed that non-opioid drugs and biologicals currently receiving transitional drug pass-through status in the OPPS would not be candidates for this policy as they are already paid separately under the OPPS and ASC payment system. We proposed that once transitional drug pass-through status expires, the non-opioid drug or biological may qualify for separate payment under the ASC payment system if it meets the proposed eligibility requirements.

Comment: Commenters requested that CMS determine the payment status of non-opioid drugs and biologicals after pass-through status expires as soon as possible through rulemaking.

Response: We thank commenters for their feedback. We will make payment determinations for applicable drugs in the appropriate calendar year rule. For example, those drugs that may be eligible for separate payment under this policy for the first time in CY 2023 will be discussed during the CY 2023 rulemaking cycle and evaluated against the appropriate eligibility criteria for that year.

Based on stakeholder feedback, we are finalizing as proposed that non-opioid pain management drugs and biologicals that function as supplies in surgical procedures that are already paid separately, or have transitional drug pass-through status under the OPPS, would not be candidates for this policy as they are already paid separately under the OPPS and ASC payment system. We also note that if a product has not received transitional pass-through status in the OPPS and ASC settings, separate payment in the ASC setting through this policy for non-opioid pain management drugs that function as surgical supplies does not preclude the manufacturer from applying for and receiving transitional pass-through status for their drug or biological if the drug or biological meets the criteria for transitional drug pass-through status. Please see section V.A., OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals, of this CY 2022 OPPS/ASC final rule for additional details on transitional pass-through payments.

(4) Regulation Text Changes

We proposed to codify our proposed criteria for separate payment for qualifying non-opioid pain management drugs and biologicals that function as surgical supplies in the regulation text for the ASC payment system in a new § 416.174. In particular, we proposed to provide in a new § 416.174(a)(1) that non-opioid pain management drugs or biologicals that function as a supply in a surgical procedure are eligible for separate payment if they are approved under a new drug application under section 505(c) of FDCA, under an abbreviated new drug application under section 505(j) of FDCA, or, in the case of a biological product, are licensed under section 351 of the PHS Act. Section 416.174(a)(1) would also provide that the drug or biological must have an FDA-approved indication for pain management or analgesia. New § 416.174(a)(2) would require that the per-day cost of the drug or biological must exceed the OPPS drug packaging threshold set annually through notice and comment rulemaking.

We also proposed to amend § 416.164(b)(6) to provide that non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174 are ancillary items that are integral to a covered surgical procedure and for which separate payment is allowed. We also proposed to amend § 416.171(b)(1) to provide that the payment rate for non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174 are

not paid an amount derived from the payment rate for the equivalent item or service under the OPPS.

We received no comments on the specific regulation text changes. As we are finalizing the two criteria as proposed, we are also finalizing the corresponding regulation text changes as proposed.

(5) Eligibility for Separate Payment in CY 2022 for Exparel, Omidria, and Other Non-Opioid Drugs or Biologicals for Pain Management

As discussed in the CY 2021 OPPS/ASC final rule with comment period, there are two products receiving separate payment in the ASC setting in CY 2021 under our current policy to pay separately for non-opioid pain management treatments that function as surgical supplies when furnished in the ASC setting (85 FR 86171). These two products are Exparel (*HCPCS Code C9290, Injection, bupivacaine liposome, 1 mg*) and Omidria (HCPCS Code J1097, *phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*). Based on the current information available to us, as we explain below, we proposed that both products would be eligible for separate payment in CY 2022 under our proposed policy. We sought comment on whether there are any other non-opioid drug or biological products that would meet the proposed criteria if finalized. We have included our evaluations of these products based on stakeholder comments in the follow sections.

(a) Eligibility for Separate Payment in CY 2022 for Exparel

We proposed that Exparel (*C9290; Injection, bupivacaine liposome, 1 mg*) would continue to receive separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply for CY 2022. As we stated in the CY 2022 OPPS/ASC proposed rule, based on CMS's internal review, we believed Exparel met criterion one. Exparel was approved by FDA with a New Drug Application (NDA #022496) on 10/28/2011.[3] Exparel's FDA-approved indication is ''in patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia (1). In adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia''.[4] No component of Exparel is opioid-based. Accordingly, we proposed that Exparel meets criterion one.

As discussed in section (3) above, for criterion two we proposed that a drug or biological would only be eligible for separate payment under this policy if its per-day cost exceeds the drug packaging threshold described in section V.B.1.a. of this final rule with comment period. The finalized per-day cost threshold for CY 2022 is $130. Using the methodology described at V.B.1.a. of this final rule with comment period, the per-day cost of Exparel exceeds the $130 per-day cost threshold. Therefore, we proposed that Exparel meets criterion two.

Based on the above discussion, we proposed that Exparel meets criteria 1 and 2, and should receive separate payment under the ASC payment system for CY 2022.

Comment: The manufacturer of Exparel, Pacira BioSciences, supported finalizing both criteria as proposed and urged CMS to finalize the proposal to pay separately for Exparel in the ASC setting. The manufacturer also noted that numerous peer-reviewed studies demonstrate that Exparel can reduce or even replace use of postsurgical opioid pain medication and lead to improved patient outcomes. Several commenters, including a hospital association and surgery associations, also supported CMS's proposal to continue to unpackage and pay separately for Exparel in the ASC setting.

Response: We appreciate the commenters' input. After reviewing the information provided during the public comment period, and as described in our proposal above, we have determined that Exparel meets criterion one for FDA approval and an FDA-approved pain management indication and that the per-day cost of Exparel exceeds the finalized $130 per-day cost threshold, meeting criterion two. Additionally, no component of Exparel is opioid-based.

After consideration of the public comments we received and consistent with the eligibility criteria we are adopting, we are finalizing our proposal that Exparel will continue to receive separate payment under the ASC payment system in CY 2022 as a non-opioid pain management drug that functions as a surgical supply.

(b) Eligibility for Separate Payment for Omidria in CY 2022

We proposed that Omidria (J1097; *Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*) would continue to receive separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply for CY 2022. Based on our internal review during the proposed rule, we stated that we believed Omidria would meet criterion one. Omidria was approved by FDA with a New Drug Application (NDA #205388) on May 30, 2014.[5] Additionally, Omidria's FDA-approved indication is as ''an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor indicated for: Maintaining pupil size by preventing intraoperative miosis; Reducing postoperative pain''.[6] No component of Omidria is opioid-based. Therefore, we proposed that Omidria would meet proposed criterion one.

Using the methodology described at V.B.1.a. of this final rule with comment period, the per-day cost of Omidria exceeds the $130 per-day cost threshold. Therefore, we proposed that Omidria meets criterion two.

Because we proposed that Omidria meets criteria one and two, we proposed that it should receive separate payment under the ASC payment system for CY 2022.

Comment: The manufacturer of Omidria, Omeros, agreed with CMS's proposal that Omidria would satisfy the proposed criteria for CY 2022 and noted their support for Omidria continuing to receive separate payment in ASC setting. The manufacturer noted that Omidria decreases the need for the opioid fentanyl during surgery and reduces opioids prescribed post operatively, but did not submit literature to support these assertions. One commenter, a hospital association, also supported CMS's proposal to continue to unpackage Omidria in the ASC setting. However, another individual commenter stated their opposition to this proposal, noting that Omidria should be treated as an incidental part of an ophthalmic surgery and not paid for separately, as, in this commenter's view, Omidria does not meaningfully ameliorate the opioid crisis, is not indicated or useful for the treatment of an opioid use disorder, and that separate payment does not provide a clinical benefit for Medicare beneficiaries. Additionally, this commenter noted that ophthalmic surgeons rarely prescribe opioids.

Response: We appreciate the public comments on our proposal. We note that we have not proposed or adopted a requirement that a product must meaningfully ameliorate the opioid crisis or have a clinically significant

[3] Exparel. FDA Letter. 28 October 2011. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/022496s000ltr.pdf.*

[4] Exparel. FDA Package Insert. 22 March 2021. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022496s035lbl.pdf.*

[5] Omidria. FDA Letter. 30 May 2014. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/205388Orig1s000ltr.pdf.*

[6] Omidria. FDA Package Insert. 08 December 2017. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf.*

impact on opioid usage. As such, after reviewing the information provided during the public comment period, and as described in our proposal above, we have determined that Omidria meets finalized criterion one because it is FDA approved and has an FDA-approved pain management indication and meets finalized criterion two because it has a per-day cost that exceeds the $130 per-day cost threshold.

After consideration of the public comments we received and our review of the criteria, we are finalizing the proposal for Omidria to continue to receive separate payment under the ASC payment system as a non-opioid pain management drug that functions as a surgical supply for CY 2022.

(c) Eligibility for Separate Payment in CY 2022 for Other Non-Opioid for Pain Management Drugs and Biologicals

We received comments on the CY 2022 OPPS/ASC proposed rule on additional non-opioid pain management drugs and biologicals that commenters believe would be eligible for separate payment in CY 2022 under our proposed policy. We have included a summary of these comments below as well as our analysis of whether these products meet the final eligibility criteria.

Comment: The manufacturer of Dextenza (J1096; *Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*), Ocular Therapeutix, commented that separate payment for Dextenza is necessary in the ASC setting for beneficiary access, as it is frequently used in that setting. The manufacturer requested continued separate payment after Dextenza's pass-through status expires.

Response: Based on CMS's internal review, we believe Dextenza meets criterion one. Dextenza was approved by FDA with a New Drug Application (NDA #208742) on November 30, 2018.[7] Dextenza's FDA-approved indication is as ''a corticosteroid indicated for the treatment of ocular pain following ophthalmic surgery''.[8] No component of Dextenza is opioid-based. Accordingly, we believe that Dextenza meets criterion one.

As discussed in section (3) above, for criterion two we proposed that a drug or biological would only be eligible for separate payment under this policy if its per-day cost exceeds the drug packaging threshold described in section V.B.1.a. of this final rule with comment period. Using that methodology, the per-day cost of Dextenza exceeds the $130 per-day cost threshold. Therefore, we believe that Dextenza meets criterion two.

We agree that Dextenza meets criteria one and two, and would be eligible to receive separate payment under the ASC payment system as a non-opioid pain management drug that functions as a surgical supply for CY 2022 if it was not already receiving separate payment-in CY 2022 as a pass-through drug. Please see section V.A. ''OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals'' of this final rule with comment period for additional details on transitional pass-through payments for drugs and biologicals, as well as section X. F. of this final rule with comment period, ''Separate Payment in CY 2022 for the Device Category, Drugs, and Biologicals with Transitional Pass-Through Payment Status Expiring between December 31, 2021, and September 30, 2022.''

Comment: The manufacturer of Dexycu (J1095; *Injection, dexamethasone 9 percent, intraocular, 1 microgram*), EyePoint Pharmaceuticals, commented that Dexycu should be eligible for separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply. An individual commenter, an ophthalmologist, noted that Dexycu is indicated for the treatment of inflammation following ocular surgery and provided summaries of several studies that discussed Dexycu's utility in controlling pain. Other commenters more broadly suggested that CMS provide separate payment for products that prevent inflammation.

Response: Based on CMS's internal review, we do not believe Dexycu meets criterion one. Dexycu was approved by FDA with a New Drug Application (NDA #208912) on February 9, 2018.[9] Dexycu's FDA-approved indication is as ''a corticosteroid indicated for the treatment of postoperative inflammation''.[10] No component of Dexycu is opioid-based. However, Dexycu does not have an FDA-approved indication for pain management or analgesia. Accordingly, we do not believe Dexycu meets criterion one.

As discussed in section II.A.3. of this final rule with comment period, for criterion two we proposed that a drug or biological would only be eligible for separate payment under this policy if its per-day cost exceeds the drug packaging threshold described in section V.B.1.a. of this final rule with comment period. Using that methodology, the per-day cost of Dexycu does exceed the $130 per-day cost threshold. Therefore, we believe Dexycu meets criterion two.

After consideration of the public comments we received and our review of the criteria, we have determined that Dexycu does not meet criteria one and, therefore, would not eligible to receive separate payment under the ASC payment system as a non-opioid pain management drug that functions as a surgical supply for CY 2022. Additionally, we note that Dexycu is already receiving separate payment through CY 2022. Please see section V.A. ''OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals'' of this final rule with comment period for additional details on transitional pass-through payments for drugs and biologicals as well as section X. F. ''Separate Payment in CY 2022 for the Device Category, Drugs, and Biologicals with Transitional Pass-Through Payment Status Expiring between December 31, 2021, and September 30, 2022.''

Comment: The manufacturer of Xaracoll, Innocoll Pharmaceuticals, commented that Xaracoll meets the two proposed CMS criteria and qualifies for separate payment as a non-opioid pain management drug that functions as a surgical supply in the ASC setting. The manufacturer also provided additional details regarding the clinical benefit of their product, including discussion of studies in which Xaracoll demonstrated significant pain relief and opioid reduction in open inguinal hernia repair.

Response: We appreciate the commenter's input. Based on CMS's internal review, we believe Xaracoll meets criterion one. Xaracoll was approved by FDA with a New Drug Application (NDA #209511) on August 28, 2020.[11] Regarding the specific FDA-approved indication requirement, Xaracoll is ''indicated in adults for placement into the surgical site to produce postsurgical analgesia for up to 24 hours following open inguinal hernia repair''.[12] No component of Xaracoll is

[7] Dextenza. FDA Letter. 30 November 2018. *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208742Orig1s000Approv.pdf.*

[8] Dextenza. FDA Labeling. 30 November 2018. *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208742Orig1s000Lbl.pdf.*

[9] Dexycu. FDA Letter. 09 February 2018. *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208912Orig1s000Approv.pdf.*

[10] Dexycu. FDA Labeling. 09 February 2018. *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208912Orig1s000Lbl.pdf.*

[11] Xaracoll. FDA Letter. 30 November 2018. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209511Orig1s000ltr.pdf.*

[12] Xaracoll. FDA Labeling. 30 November 2018. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209511s000lbl.pdf.*

opioid-based. Accordingly, we believe that Xaracoll meets criterion one.

As discussed in section II.A.3. of this final rule with comment period, for criterion two we proposed that a drug or biological would only be eligible for separate payment under this policy if its per-day cost exceeds the drug packaging threshold described in section V.B.1.a. of this final rule with comment period. Using that methodology, the per-day cost of Xaracoll exceeds the $130 per-day cost threshold. Therefore, we believe that Xaracoll meets criterion two.

After consideration of the public comments we received and our review of the finalized criteria, we have determined that Xaracoll meets criteria one and two, and are approving Xaracoll (C9089; *Bupivacaine, collagen-matrix implant, 1 mg*) to receive separate payment under the ASC payment system as a non-opioid pain management drug that functions as a surgical supply for CY 2022.

Comment: The manufacturer of Zynrelef, Heron Therapeutics, stated how Zynrelef meets CMS's proposed criteria for separate payment in the ASC setting and should be receive separate payment in that setting. The manufacturer also provided additional details regarding the clinical benefit of their product, including studies where Zynrelef demonstrated reduced opioid use.

Response: We appreciate the commenter's input. Based on CMS's internal review, we believe Zynrelef meets criterion one. Zynrelef was approved by FDA with a New Drug Application (NDA #211988) on May 12, 2021.[13] Regarding the specific FDA-approved indication requirement, Zynrelef is ''indicated in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy and total knee arthroplasty''.[14] No component of Zynrelef is opioid-based. Accordingly, we believe that Zynrelef meets criterion one.

As discussed in section (3) above, for criterion two we proposed that a drug or biological would only be eligible for separate payment under this policy if its per-day cost exceeds the drug packaging threshold described in section V.B.1.a. of this final rule with comment period. Using that methodology, the per-day cost of Zynrelef exceeds the $130 per-day cost threshold. Therefore, we believe that Zynrelef meets criterion two.

After consideration of the public comments we received and our review of the finalized criteria, we have determined that Zynrelef meets criteria one and two, and are approving Zynrelef (C9088; *Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg*) to receive separate payment under the ASC payment system as a non-opioid pain management drug that functions as a surgical supply for CY 2022.

Comment: The manufacturer of Anjeso (HCPCS code J1738; *Injection, meloxicam, 1 mg*), Baudax Bio, expressed support for policies that encourage the use of non-opioid pain alternatives. In their comment, Baudax Bio discussed the clinical benefits of their product.

Response: We appreciate the commenter's input. Based on CMS's internal review, we believe Anjeso meets criterion one. Anjeso was approved by FDA with a New Drug Application (NDA #210583) on February 20, 2020.[15] Anjeso's FDA-approved indication is ''indicated for use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics''.[16] No component of Anjeso is opioid-based. Accordingly, we believe that Anjeso meets criterion one.

As discussed in section II.A.3. of this final rule with comment period, for criterion two we proposed that a drug or biological would only be eligible for separate payment under this policy if its per-day cost exceeds the drug packaging threshold described in section V.B.1.a. of this final rule with comment period. Using that methodology, the per-day cost of Anjeso does not exceed the $130 per-day cost threshold. Therefore, we do not believe that Anjeso meets criterion two.

After consideration of the public comments we received and our review of the finalized criteria, we have determined that Anjeso meets criteria one but not criterion two, and would not be eligible to receive separate payment under the ASC payment system as a non-opioid pain management drug that functions as a surgical supply for CY 2022. However, Anjeso remains on transitional pass-through status throughout CY 2022 and accordingly, is already receiving separate payment in the HOPD and ASC settings for CY 2022. Please see section V.A., OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals, of this final rule with comment period for additional details on transitional pass-through payments for drugs and biologicals.

Comment: Several commenters, including hospital and professional associations, recommended separate payment for Ofirmev, IV acetaminophen, stating they believed it decreased use of post-operative opioids.

Response: We appreciate the commenters' input. Based on CMS's internal review, we believe Ofirmev meets criterion one. Ofirmev was approved by FDA with a New Drug Application (NDA #022450) on October 2, 2010.[17] Ofirmev's FDA-approved indication is ''management of mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics, and reduction of fever''.[18] No component of Ofirmev is opioid-based. Accordingly, we believe that Ofirmev meets criterion one.

As discussed in section (3) above, under criterion two a drug or biological is only eligible for separate payment if its per-day cost exceeds the drug packaging threshold described in section V.B.1.a. of this final rule with comment period. Using the methodology described at V.B.1.a. of this final rule with comment period, the per-day cost of Ofirmev does not exceed the $130 per-day cost threshold. Therefore, we do not believe Ofirmev meets criterion two.

After consideration of the public comments we received and our review of the criteria, we have determined that Ofirmev meets criteria one but not criterion two and is not eligible to receive separate payment under the ASC payment system as a non-opioid pain management drug that functions as a surgical supply for CY 2022.

Comment: Several commenters, including professional and hospital associations, commented that classes of drugs, such as NSAIDS, including IV ibuprofen and IV ketorolac, may reduce opioid usage if CMS paid separately for them. However, they did not request that CMS consider a specific non-opioid product for separate payment in the ASC setting.

Response: We thank commenters for their comments. For both of these

[13] Zynrelef. FDA Letter. 05 May 2021. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/211988Orig1s000ltr.pdf.*

[14] Zynrelef. FDA Labeling. 05 May 2021. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211988s000lbl.pdf.*

[15] Anjeso. FDA Letter. 02 February 2020. *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/210583Orig1s000Approv.pdf.*

[16] Anjeso. FDA Labeling. 02 February 2020. *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/210583Orig1s000lbl.pdf.*

[17] Ofirmev. FDA Letter. 02 November 2010. *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022450Orig1s000Approv.pdf.*

[18] Ofirmev. FDA Labeling. 02 November 2010. *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022450Orig1s000Lbl.pdf.*

products, we did not receive recommendations for a specific product, for a specific FDA approval, or from a specific manufacturer. We note that based on our review of these products, we do believe IV ibuprofen and IV ketorolac products, which have FDA approval and an FDA-approved indication for pain management or as an analgesic, would satisfy criterion one. However, based on our review of these products, using the methodology described at V.B.1.a. of this final rule with comment period, the per-day costs of HCPCS code 1741 (*Injection, ibuprofen, 100 mg)* and HCPCS code J1885 (*Injection, ketorolac tromethamine, per 15 mg)* do not exceed the packaging threshold for criterion two.

Comment: Commenters requested CMS consider the clinical value of Prialt (HCPCS Code J2278; *Injection, ziconotide, 1 microgram*) and Dsuvia, a sufentanil sublingual tablet, for separate payment in the ASC setting

Response: Prialt is not eligible for separate payment under our final policy because it is not a drug that functions as a supply in a surgical procedure and is already receiving separate payment. Dsuvia is not eligible for separate payment under our final policy because it contains an opioid and therefore is not a non-opioid drug. We are not revising our policy to provide separate payment for opioid pain management products for CY 2022.

As previously explained above, we are not modifying the eligibility criteria for our policy to include such products. However, we appreciate these comments and suggestions from stakeholders and will take them into consideration for future rulemaking.

(6) Comment Solicitation on Policy Modifications and Potential Additional Criteria for Revised Payment for Non-Opioid Pain Management Treatments

In addition to the proposed eligibility criteria above, we also sought comment on potential policy modifications and additional criteria that may help further align this policy with the intent of section 1833(t)(22) of the Act. Below we discuss potential additional criteria. We noted in the CY 2022 OPPS/ASC proposed rule that, depending on the public comments we received and our continued consideration of these potential criteria, we may adopt these criteria as part of our final policy and include them in the final regulation text; accordingly, we provided substantial details, explanations, and considerations about these potential criteria. We welcomed input from stakeholders on these and any additional policy modifications or criteria they believe would enhance our proposed policy. We also sought comment on other barriers to access to non-opioid pain management products that may exist, and to what extent our policies under the OPPS or ASC payment system could be modified to address these barriers.

Comment: A few comments from providers and drug manufacturers discussed additional barriers they faced in providing non-opioid pain management products. One commenter recommended CMS provide education to providers on non-opioid pain medications and to encourage patients to ask their providers about which medications they are being prescribed. One commenter noted that not allowing separate payment for non-opioid products in the HOPD setting limits the expansion of patient access to non-opioid therapies in new geographic areas. Another commenter noted that rural and underserved areas have been disproportionately harmed by opioid addiction and that geography, lack of provider education and training, and payment and coverage for these services may be barriers to treatment in these communities.

Response: We are committed to implementing measures to combat the opioid epidemic. We appreciate stakeholders' comments in response to this solicitation. We will take these comments into consideration for future rulemaking.

Comment: Many commenters appreciated CMS soliciting comment on potential additional criteria in the proposed rule. A few commenters recommended that CMS not finalize additional criteria based on responses to the comment solicitations. Rather, they suggested CMS finalize the two proposed criteria and assess the policy in the future to assess whether additional criteria are warranted.

Response: We thank commenters for their input. We are not finalizing additional criteria or policy modifications based on the comments were received in response to the comment solicitations in the CY 2022 OPPS/ASC proposed rule. Please see the following sections for a summary of the comments received.

(a) Utilization of the Product

We have historically used utilization as a metric to determine whether a change in our payment policy was necessary to determine whether our policies create a disincentive to use non-opioid alternatives. For example, as previously discussed, Exparel's decreasing utilization in the ASC setting caused us to propose to pay separately for non-opioid pain management drugs that function as surgical supplies in the ASC setting. We have used currently available claims data in prior years to analyze the payment and utilization patterns associated with specific non-opioid alternatives to determine whether our packaging policies may have reduced the use of non-opioid alternatives. We believe that higher utilization may be a potential indicator that the packaged payment is not causing an access to care issue and that the payment rate for the primary procedure adequately reflects the cost of the drug or biological. We also believe decreased utilization could potentially indicate that our packaging policy is discouraging use of a drug or biological and that providers are choosing less expensive treatments. We note that it is difficult to attribute product-specific changes in utilization to our packaging policies alone. Nonetheless, while we acknowledge certain limitations of utilization data, we believe analyzing utilization either on a product-specific basis or on a broader basis could be an important criterion in determining whether separate payment is warranted for a non-opioid pain management alternative.

Therefore, we solicited comment on whether specific evidence of reduced utilization should be part of our evaluation and determination as to whether a non-opioid pain management product should qualify for modified payment. This data may help to demonstrate that our packaging policies are causing an access issue for these products. Additionally, we realize that new products to the market may not have utilization data available, or reliable utilization data may be difficult to obtain for some products; therefore, we also requested comment on whether utilization data requirements should vary based on the newness of a product or its FDA marketing approval date.

Comment: Generally, commenters did not support adding a utilization requirement criterion. Several commenters stated that utilization data was useful in the original analysis to establish the original policy in the ASC setting, but they believe would be inappropriate to require new products to prove they are disincentivized by CMS packaging policies. These commenters noted it would take significant time for this data to be available after a new drug was introduced to the market. Additionally, several comments stated that utilization data is imperfect, as CMS described in the CY 2022 OPPS/ASC proposed rule.

Response: We thank commenters for their feedback on a potential utilization requirement. However, we are not finalizing any policy modifications, including adopting a utilization requirement, for CY 2022. We will take these comments into consideration for future rulemaking.

(b) FDA-Approved Indication for Pain Management or Analgesia for the Drug or Biological Product

As previously discussed, section 1833(t)(22)(A) of the Act specifically refers to reviews of opioid and evidence-based non-opioid products for pain management. We believe the majority of drugs and biologicals that would meet the requirements of our proposed policy would already have FDA approval as a pain management drug or as an analgesic. However, we acknowledge there may be other non-opioid products that would benefit from inclusion under this policy, but do not have a specific FDA-approved indication for pain management or analgesia, and would not satisfy criterion one. Therefore, we solicited comment on whether we should allow certain FDA-approved drugs and biologicals to be eligible for separate payment under this policy without a specific FDA-approved indication for pain management or as an analgesic drug. In lieu of an FDA-approved indication for pain management or analgesia, we sought comment on whether it would be appropriate to approve a product for inclusion under this policy if the pain-management or analgesia attributes of the drug or biological are recognized by a medical compendium. Similarly, we sought comment as to whether we should consider specialty society or national organization (such as a national surgery organization) recommendations of non-opioid pain management products that function as surgical supplies and reduce opioid use in the ASC setting, as evidence that a product meets criterion one, when a drug or biological does not have an FDA-approved indication for pain management or analgesia.

Comment: Some commenters were supportive of CMS taking into consideration other factors, such as specialty society endorsements, medical compendia, or inclusion in clinical practice guidelines, as part of the qualifying criteria if an FDA-approved indication for pain management or analgesia was not present. Commenters stated a specific FDA-approved indication may be too restrictive as some products may be used off-label for pain management. A few commenters suggested CMS take an individualized and holistic approach to each drug it evaluates, and therefore, consider association recommendations outside of FDA-approved indications. Commenters thought this would support increased access to drugs for off-label uses.

Response: We appreciate the comments received as a part of this specific comment solicitation; however, for CY 2022, we are not making any policy modifications based on the public comments we received in response to this comment solicitation.

(c) Peer-Reviewed Literature Requirement Comment Solicitation

We note that section 1833(t)(22)(B) of the Act requires the Secretary to focus on covered OPD services (or groups of services) assigned to a comprehensive ambulatory payment classification, ambulatory payment classifications that primarily include surgical services, and other services determined by the Secretary that generally involve treatment for pain management. Therefore, we solicited comment as to whether we should only adopt a payment revision for drugs and biologicals that function as surgical supplies in the ASC setting when those products have evidence in peer-reviewed literature supporting that the product actually decreases opioid usage associated with the surgical procedure. We believe this may be appropriate to ensure Medicare payment policies would not financially incentivize use of opioids rather than evidence-based non-opioid alternative treatments, as required by section 1833(t)(22)(A)(iii) of the Act. Specifically, we sought comment as to whether the drug or biological's use in a surgical procedure as a non-opioid pain management product should be supported by peer-reviewed literature demonstrating a clinically significant decrease in opioid usage compared to the standard of care, and we sought comment on whether such decreases in opioid usage should be sustained decreases that continue into the post-operative period.

Additionally, we sought input from commenters as to what they believe the requirements for peer-reviewed literature should be. For example, we solicited stakeholder feedback as to whether peer-reviewed literature should demonstrate that use of the drug or biological results in at least one, or several, of the following: decreased post-operative opioid use following surgery, decreased opioid misuse following surgery, or decreased opioid use disorder and dependency following surgery.

Additionally, we asked stakeholders if specific thresholds are necessary to determine whether these decreases are statistically and clinically significant and whether the decreases should simply be measured against placebo or the standard of care. We also requested information on how stakeholders would define the standard of care in these circumstances. In the proposed rule we stated, when evaluating literature, we would expect to examine the study methods, sample size, limitations, possible conflicts of interest, patient populations studied, and how the evidence supports the conclusion that the product can serve as a non-opioid pain management product and provide a clinically significant reduction in opioid use that continues into the post-operative period. However, we welcomed input from stakeholders about additional aspects of these studies that they believe CMS should focus on for this potential criterion. Additionally, we stated we would expect to use our discretion to assess whether the submitted studies meet these criteria, as well as for clinical applicability, literature integrity, and potential biases in consultation with our clinical advisors.

In order to provide stakeholders with some examples of what supporting evidence CMS may consider for this potential criterion, we stated in the proposed rule that we believed it would be helpful for CMS to receive literature demonstrating that use of a non-opioid drug or biological results in a statistically and clinically significant decreased day supply of outpatient opioids prescribed after surgery discharge compared to the generally accepted standard of care, or a statistically and clinically significant decreased morphine milligram equivalents (MME) per opioid dose prescribed after surgery discharge compared to the generally accepted standard of care. We would consider the generally accepted standard of care to include pain management therapy a patient would receive in the absence of the non-opioid alternative, such as the use of localized analgesia and/or an opioid. As previously discussed, we would then expect the use of a non-opioid pain management drug or biological to result in a decline in opioids used compared to the pain management therapy a patient would receive in the absence of the non-opioid alternative. We would expect this decline in opioids to include a decreased number of opioids received by a patient intraoperatively, post-operatively, and most significantly at discharge. We solicited comment on additional examples or measures that

would be beneficial for CMS to take into consideration. Additionally, we sought comment on whether we should require a specific objective measure for this criterion. We also sought input on how to assess whether changes are statistically and clinically significant. We requested comment on whether stakeholders believe evidence of statistical significance should be sufficient, or whether stakeholders believe the literature should also demonstrate clinically significant differences between treatment groups as well.

Comment: Many commenters did not support CMS finalizing any additional criteria, including a peer-reviewed literature requirement. A few commenters disagreed that a peer-reviewed literature requirement was necessary as they believed an FDA-approved indication for pain management or analgesia would be sufficient. Several commenters suggested CMS collect, review, and consider peer-reviewed literature, but not explicitly require it.

Response: We appreciate the comments received as a part of this specific comment solicitation; however, for CY 2022, we are not making any policy modifications based on the public comments we received in response to this comment solicitation. We will take these comments into consideration for future rulemaking.

Comment: A few commenters supported CMS requiring peer-reviewed literature that demonstrates that the drug in question reduces opioid use in the post-operative period. One commenter specified which type of literature endpoints would be important to incorporate into our review process. Specifically, one drug manufacturer recommended that CMS require that use of a drug demonstrate a significant reduction in the need for opioids and increase the number of patients who are opioid free in a randomized, well-controlled, head-to-head clinical trial versus an active comparator. A number of commenters requested that CMS provide separate payment for evidence-based, non-opioid pain management drugs. Specifically, in regards to peer-reviewed literature, MedPAC asserted that separately payable status should only be granted when evidence in peer-reviewed publications indicates that the drug in question reduces the use of opioids. Other commenters supported a criterion that requires a product to demonstrate the ability to replace, reduce, or avoid opioid use or the quantity of opioids prescribed.

Response: We thank commenters for their detailed comments. We agree it is important that a non-opioid pain management product serve as an alternative to an opioid, and therefore replace, reduce, or avoid opioid use.

We once again thank commenters for their detailed insights on this comment solicitation; however, for CY 2022, we are not making any policy modifications based on the public comments we received in response to this comment solicitation. We will take these comments into consideration for future rulemaking.

(d) Alternative Payment Mechanisms for Non-Opioid Drugs and Biologicals

As previously discussed, for CY 2022, we proposed to pay separately at ASP+6 percent for non-opioid pain management drugs and biologicals that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and meet our other proposed criteria. Section 1833(t)(22)(A)(iii) of the Act requires the Secretary to consider the extent to which revisions to payments (such as the creation of additional groups of covered OPD services to classify separately those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management. Accordingly, separate payment is not the only possible revision that may be appropriate. We sought comment on additional payment mechanisms that may be appropriate aside from separate payment. For instance, we requested feedback from stakeholders as to whether a single, flat add-on payment, or separate APC assignment, for products or procedures that use a product that meets eligibility criteria would be preferable to separate payment. We note that any revisions the Secretary determines appropriate under section 1833(t)(22)(C) of the Act must be applied in a budget neutral manner under section 1833(t)(9)(B) of the Act. We also sought input from stakeholders on any other innovative payment mechanisms for eligible non-opioid drugs and biologicals for pain management.

Comment: Most commenters opposed any other payment methodologies aside from paying separately for non-opioid pain management drugs or biologicals at ASP+6 percent. Several commenters contended that an add-on payment would not be appropriate because this would create differentials in payment across care settings, such as physician offices, and emphasized that stakeholders are more familiar with the ASP payment methodology. Some commenters also emphasized that drugs and biologicals are generally paid at ASP+6 percent when furnished in the physician office setting and encouraged CMS to pay ASP+6 percent under this policy to ensure payment parity across the different treatment settings.

One commenter asked that CMS apply its final payment policy for 340B-acquired drugs, to pay for non-opioid drug products at ASP minus 22.5 percent instead of ASP+ 6 percent. Additionally, one commenter asked that CMS create new CPT codes in order to account for the work associated with opioid-sparing therapies furnished by surgeons.

Response: We appreciate the comments received as a part of this specific comment solicitation; however, for CY 2022, we are not making any policy modifications based on the public comments we received in response to this comment solicitation. We will take these comments into consideration for future rulemaking.

(e) Non-Drug Products

In the CY 2022 OPPS/ASC proposed rule, we stated we were also interested in information on any non-opioid non-drug products that function as surgical supplies that commenters believe should be eligible for separate payment under this policy. Although we have not currently identified any non-opioid pain management non-drug products that are disincentivized by CMS packaging policies based on utilization data, we believe it is reasonable to assume that if disincentives exist for the use of non-opioid pain management drugs and biological products under the ASC payment system, they may also exist for non-opioid, non-drug products under the ASC payment system. If this is the case, we would like to address these disincentives given the severity and importance of combatting the opioid epidemic, regardless of whether the non-opioid product is a drug, biological, or non-drug product. We remain interested in whether there are any non-opioid non-drug products that may meet the proposed eligibility criteria and should qualify for separate or modified payment as discussed in section (d) above, in the ASC setting. Similarly, we also sought comment on whether there are unique qualities of non-drug products that would make revised payment in the HOPD setting appropriate instead of, or in addition to, the ASC setting.

We sought comment on whether it is appropriate to require non-drug products to meet the same criteria being proposed for drugs and biologicals. Additionally, we sought comment from

stakeholders on whether they believe it would be appropriate to create a broad category for non-drug products, or if a more limited category, such as for devices, would be appropriate. Specifically, we sought comment on whether there is information in the FDA approval for devices that would be an appropriate criterion to determine eligibility for separate payment, similar to how we proposed to require FDA approval with an FDA-approved indication for pain management or analgesia for drugs and biologicals. We sought comment on whether, if the non-drug product is a ''device'' as defined in section 201(h) of FDCA, the device should have received FDA premarket approval (PMA), grant of a *de novo* request, 510(k) clearance or meet an exemption from premarket review. Finally, we solicited comment on all aspects of an extension of our current policy to include appropriate products that are not drugs or biologicals.

We also sought comment on how peer-reviewed literature and utilization claims data could be used as potential criteria for a policy that would apply to non-drug products. Additionally, should a payment revision be determined necessary, we solicited comment on appropriate payment mechanisms for non-opioid, non-drug products, including assigning the non-drug product to its own APC to ensure that the product is paid separately or establishing an add-on adjustment for the cost of the non-drug product in addition to the payment for the APC to which the non-drug product is assigned. Additionally, we sought comment on whether it would be appropriate to subject non-drug products to a cost threshold similar to the one we proposed to apply to drugs and biologicals.

Comment: A few commenters supported CMS exploring a payment adjustment for non-opioid, non-drug items, including items such as devices. Some commenters discussed the benefit of spinal cord stimulators, and one commenter recommended an add-on payment for a narrowly constructed payment category, such as spinal cord stimulators. Commenters also cited the CMS prior authorization policy on spinal cord stimulators as inappropriately creating barriers to access to these devices, as beneficiaries could be prescribed opioids for longer periods of time while waiting for prior authorization to be approved. Commenters recommended CMS provide separate payment for nerve blocks, pain blocks (represented by CPT codes 64415, 64416, 64417, 64445, 64446, 64447, 64448, 64450), joint injections, and neuromodulation.

Some commenters stated that barriers for non-drug items are often more severe in the ASC setting. Commenters also suggested CMS consider payment methodologies for various other non-drug items, including for multi-modal pain management ERAS protocols, physical therapy, acupuncture, massage therapy, ON–Q pain relief system, devices that use ice water, dry needling, THC oil applied topically, and polar ice devices.

Commenters pointed to the opioid-sparing abilities of some of these products. For example, commenters noted that spinal cord stimulators are useful in reducing opioid usage for chronic pain patients. Commenters urged CMS to change payment polices to make spinal cord stimulators a front-line option in combating chronic pain.

Response: We appreciate the responses from commenters on this topic. As discussed in prior rulemaking (85 FR 85899), we have not found compelling evidence for non-drug, non-opioid pain management alternatives that commenters described to warrant separate payment under the OPPS or ASC payment system. For CY 2022, we are not finalizing any policy modifications in response to the comments we received on this comment solicitation. We will take these comments into consideration for future rulemaking.

Comment: Some commenters recommended that criteria similar to those proposed for drug items also apply to non-drug items, including a potential requirement for peer-reviewed literature demonstrating that the product significantly limits or eliminates prescription opioids.

Response: We thank commenters for their feedback regarding potential criteria for non-drug items and how we may incorporate non-drug products into our non-opioid pain management packaging policy in the future. We will take these comments into consideration for future rulemaking.

(f) Coinsurance Waiver Request

Comment: Multiple commenters, including providers and the manufacturer of Prialt, an intrathecal drug, requested CMS waive the 20 percent coinsurance requirement for non-opioid pain management drugs. Specifically, these commenters discussed that waiving coinsurance for non-opioid drugs that are indicated for severe chronic pain in patients requiring intrathecal therapy could bolster patient access

Response: The services described here, including intrathecal therapy, do not meet the statutory requirements process for ''additional preventive services'' in section 1861(ddd)(1) of the Act that would be subject to coinsurance waiver under 1833(a)(1)(W). Providers may waive coinsurance amounts only if they comply with applicable law, including the Federal Anti-Kickback Statute and the civil monetary penalty provision prohibiting inducements to beneficiaries. We note that the drugs these commenters describe are already paid separately. Additionally, the intrathecal drug, Prialt, frequently described by commenters, does not function as a supply to a surgical procedure. As such, it would not qualify under our current policy to pay separately in the ASC setting for non-opioid pain management drugs and biologicals that function as surgical supplies. However, we appreciate the commenters' input about the potential value of these drugs.

Summary of Finalized Policy

As discussed in the preceding sections, after consideration of the public comments we received, we are finalizing the proposed policy for CY 2022 to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA-approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPS/ASC drug packaging threshold for CY 2022. As noted above, we are finalizing the proposed regulation text changes at § 416.164(a)(4) and (b)(6), § 416.171(b)(1), and § 416.174 as proposed. We determined that four products are eligible for separate payment in the ASC setting under our final policy for CY 2022. Future products, or products not discussed in this rulemaking that may be eligible for separate payment under this policy will be evaluated in future notice and comment rulemaking. We will continue to analyze the issue of access to non-opioid pain management alternatives in the OPPS and the ASC settings as part of any subsequent reviews we conduct under section 1833(t)(22)(A)(ii) of the Act, which would be discussed in future notice and comment rulemaking. We will also continue to evaluate whether there are other non-opioid pain management alternatives for which our payment policy should be revised to allow separate payment in future rulemaking. Table 4 below lists the four

drugs that meet our finalized criteria and will receive separate payment under the ASC payment system when furnished in the ASC setting for CY 2022.

BILLING CODE 4120–01–P

TABLE: SUMMARY OF PRODUCTS MEETING CMS'S CRITERIA FOR SEPARATE PAYMENT IN THE ASC SETTING UNDER THE NON-OPIOID PAIN MANAGEMENT DRUGS THAT FUNCTION AS A SURGICAL SUPPLY PACKAGING POLICY

HCPCS Code	Long Descriptor	Final CY 2022 OPPS Status Indicator (SI)*	Final CY 2022 ASC Payment Indicator (PI)*
C9290	Injection, bupivacaine liposome, 1 mg	N	K2
J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	N	K2
C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	N	K2
C9089	Bupivacaine, collagen-matrix implant, 1 mg	N	K2

*Please see ASC addenda BB for applicable payment rates, OPPS addenda D1 for SI definitions, and ASC addenda DD1 for PI definitions. All are available via the internet on the CMS website.

BILLING CODE 4120–01–C

4. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85902 through 85903), we applied this policy and calculated the relative payment weights for each APC for CY 2021 that were shown in Addenda A and B of the CY 2021 OPPS/ASC final rule with comment period (which were made available via the internet on the CMS website) using the APC costs discussed in sections II.A.1. and II.A.2. of the CY 2021 OPPS/ASC final rule with comment period. For CY 2022, as we did for CY 2021, we proposed to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2022 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing any and all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For CY 2022, as we did for CY 2021, we proposed to continue to standardize all of the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For CY 2022, as we did for CY 2021, we proposed to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

We note that in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015) and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61365 through 61369), we discuss our policy, implemented on January 1, 2019, to control for unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at excepted off-campus provider-based department (PBD) at a reduced rate. While the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the policy has a negligible effect on the scalar. Specifically, under this policy, there is no change to the relativity of the OPPS

payment weights because the adjustment is made at the payment level rather than in the cost modeling. Further, under this policy, the savings that result from the change in payments for these clinic visits are not budget neutral. Therefore, the impact of this policy will generally not be reflected in the budget neutrality adjustments, whether the adjustment is to the OPPS relative weights or to the OPPS conversion factor. For a full discussion of this policy, we refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142).

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2022 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we proposed to compare the estimated aggregate weight using the CY 2021 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2022 unscaled relative payment weights.

For CY 2021, we multiplied the CY 2021 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2019 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2022, we proposed to apply the same process using the estimated CY 2022 unscaled relative payment weights rather than scaled relative payment weights. We proposed to calculate the weight scalar by dividing the CY 2021 estimated aggregate weight by the unscaled CY 2022 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Click on the link labeled ''CY 2022 OPPS/ASC Notice of Proposed Rulemaking'', which can be found under the heading ''Hospital Outpatient Prospective Payment System Rulemaking'' and open the claims accounting document link at the bottom of the page, which is labeled ''2022 NPRM OPPS Claims Accounting (PDF)''.

We proposed to compare the estimated unscaled relative payment weights in CY 2022 to the estimated total relative payment weights in CY 2021 using CY 2019 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we proposed to adjust the calculated CY 2022 unscaled relative payment weights for purposes of budget neutrality. We proposed to adjust the estimated CY 2022 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4436 to ensure that the proposed CY 2022 relative payment weights are scaled to be budget neutral. The proposed CY 2022 relative payment weights listed in Addenda A and B to the CY 2022 OPPS/ASC proposed rule (which are available via the internet on the CMS website) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1 and II.A.2 of the CY 2022 OPPS/ASC proposed rule (86 FR 42026).

Section 1833(t)(14) of the Act provides the payment rates for certain specified covered outpatient drugs (SCODs). Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2 of the CY 2022 OPPS/ASC proposed rule (86 FR 42131 through 42133) is included in the budget neutrality calculations for the CY 2022 OPPS.

We did not receive any public comments on the proposed weight scalar calculation. Therefore, we are finalizing our proposal to use the calculation process described in the proposed rule, without modification, for CY 2022. Using updated final rule claims data, we are updating the estimated CY 2022 unscaled relative payment weights by multiplying them by a weight scalar of 1.4416 to ensure that the final CY 2022 relative payment weights are scaled to be budget neutral. The final CY 2022 relative payments weights listed in Addenda A and B of this final rule with comment period (which are available via the internet on the CMS website) were scaled and incorporate the recalibration adjustments discussed in sections II.A.1 and II.A.2 of this final rule with comment period.

B. Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25435), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2020 forecast of the FY 2022 market basket increase, the proposed FY 2022 IPPS market basket update was 2.5 percent.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced 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 defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (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 ''MFP adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment, and then revised this methodology, as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509). In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25435), the proposed MFP adjustment for FY 2022 was 0.2 percentage point.

Therefore, we proposed that the MFP adjustment for the CY 2022 OPPS is 0.2 percentage point. We also proposed that if more recent data become subsequently available after the publication of the CY 2022 OPPS/ASC proposed rule (for example, a more recent estimate of the market basket increase and/or the MFP adjustment), we will use such updated data, if appropriate, to determine the CY 2022 market basket update and the MFP adjustment, which are components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in the CY 2022 OPPS/ASC final rule.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we proposed for CY 2022 an OPD fee schedule increase factor of 2.3 percent for the CY 2022 OPPS (which is the proposed estimate of the hospital inpatient market basket percentage increase of 2.5 percent, less the proposed 0.2 percentage point MFP adjustment).

We proposed that hospitals that fail to meet the Hospital OQR Program reporting requirements would be subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. For further discussion of the Hospital OQR Program, we refer readers to section XIV. of the proposed rule.

To set the OPPS conversion factor for 2022, we proposed to increase the CY 2021 conversion factor of $82.797 by 2.3 percent. In accordance with section 1833(t)(9)(B) of the Act, we proposed further to adjust the conversion factor for CY 2022 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We proposed to calculate an overall budget neutrality factor of 1.0012 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2022 IPPS wage indexes to those payments using the FY 2021 IPPS wage indexes, as adopted on a calendar year basis for the OPPS.

For the CY 2022 OPPS, we proposed to maintain the current rural adjustment policy, as discussed in section II.E. of the CY 2022 OPPS/ASC proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

We proposed to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of the CY 2022 OPPS/ASC proposed rule. We proposed to calculate a CY 2022 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2022 payments under section 1833(t) of the Act, including the proposed CY 2022 cancer hospital payment adjustment, to estimated CY 2022 total payments using the CY 2021 final cancer hospital payment adjustment, as required under section 1833(t)(18)(B) of the Act. The proposed CY 2022 estimated payments applying the proposed CY 2022 cancer hospital payment adjustment were the same as estimated payments applying the CY 2021 final cancer hospital payment adjustment. Therefore, we proposed to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 1833(t)(18)(C), as added by section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255), we are applying a budget neutrality factor calculated as if the proposed cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we applied as stated in section II.F. of the proposed rule.

For the CY 2022 OPPS/ASC proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2022 would equal approximately $1.03 billion, which represented 1.24 percent of total projected CY 2022 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.92 percent estimate of pass-through spending for CY 2021 and the 1.24 percent estimate of proposed pass-through spending for CY 2022, resulting in a proposed decrease to the conversion factor for CY 2022 of 0.32 percent.

Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2022. We estimated for the proposed rule that outlier payments would be 1.06 percent of total OPPS payments in CY 2021; the 1.00 percent for proposed outlier payments in CY 2022 would constitute a 0.06 percent decrease in payment in CY 2022 relative to CY 2021.

For the CY 2022 OPPS/ASC proposed rule, we also proposed that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we proposed to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of 0.3 percent (that is, the proposed OPD fee schedule increase factor of 2.3 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2022 of $82.810 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.647 in the conversion factor relative to hospitals that met the requirements).

In summary, for 2022, we proposed to use a reduced conversion factor of $82.810 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.647 in the conversion factor relative to hospitals that met the requirements).

For 2022, we proposed to use a conversion factor of $84.457 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 2.3 percent for CY 2022, the required proposed wage index budget neutrality adjustment of approximately 1.0012, the proposed cancer hospital payment adjustment of 1.0000, and the proposed adjustment of 0.32 percentage point of projected OPPS spending for the difference in pass-through spending that resulted in a proposed conversion factor for CY 2022 of $84.457.

Comment: Two commenters request that the OPD fee schedule update factor be larger than the proposed 2.3 percent increase. One commenter cited a MedPAC study [19] that reported for 2019 that the aggregate Medicare margin for inpatient hospital providers was −8.7 percent among all inpatient hospital providers, and that the median Medicare margin was −1 percent for relatively efficient providers. This commenter appeared to request the OPD fee schedule update factor be increased sufficiently to substantially reduce the aggregate margin for hospital providers. The commenter also mentioned that the annual Consumer Price Index was 5.4 percent which was over 3 percentage points higher than the proposed 2.3 percent OPD fee schedule increase. The second commenter, a state hospital association, claimed that unspecified recent payment cuts for outpatient hospital services have hurt the financial position of hospitals in their state. The commenter asks us to identify additional ways to increase hospital payment more than the proposed 2.3 percent OPD fee schedule increase.

Response: The OPD fee schedule update factor is designed to maintain a consistent level of payment for outpatient hospital services in Medicare year over year after taking into account changes in medical inflation and business productivity. In addition, the

[19] Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy,* v, 499 (Mar. 2021), *http://medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf.*

OPPS conversion factor is not designed to redress payment reductions made in a non-budget neutral manner. The MedPAC study cited by one of the commenters reported, in addition to the aggregate Medicare margin for inpatient hospital providers, that the median margin for Medicare spending for relatively efficient hospitals was around −1 percent for 2019. The same MedPAC study also recommended a 2.0 percent increase in outpatient hospital spending for 2022, which is actually lower than our proposed conversion factor update of 2.3 percent.

The same commenter also suggested that the Consumer Price Index may be a better measure of medical inflation than the hospital market basket index used by CMS. The percentage change in the hospital market basket reflects the average change in the price of goods and services purchased by hospitals in order to provide medical care. A general measure of health care inflation (such as the Consumer Price Index for Medical Care Services) would not be appropriate as it is not specific to hospital medical services and is not reflective of the input price changes experienced by hospitals but rather the inflation experienced by the consumer for their medical expenses.

Comment: Two commenters supported our proposed CY 2022 OPD fee schedule increase factor percentage increase of 2.3 percent.

Response: We appreciate the support of the commenters.

After reviewing the public comments that we received, we are finalizing these proposals with modification. For CY 2022, we proposed to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act (discussed in section II.F. of this final rule with comment period). Based on the final rule updated data used in calculating the cancer hospital payment adjustment in section II.F. of this final rule with comment period, the target payment-to-cost ratio for the cancer hospital payment adjustment, which was 0.90 for CY 2021, is also 0.90 for CY 2022. As a result, we are applying a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment.

For this CY 2022 OPPS/ASC final rule with comment period, as published in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45214), based on IGI's 2021 second quarter forecast with historical data through the first quarter of 2021, the hospital market basket update for CY 2022 is 2.7 percent and the estimate of the 10-year moving average growth of MFP for FY 2022 is 0.7 percent.

We note that as a result of the modifications in final policy for the CY 2022 wage index we are also including a change to the wage index budget neutrality adjustment so that the final overall budget neutrality factor of 1.0000 would apply for wage index changes. This adjustment is comprised of a 1.0001 budget neutrality adjustment, using our standard calculation of comparing proposed total estimated payments from our simulation model using the final FY 2022 IPPS wage indexes to those payments using the FY 2022 IPPS wage indexes, as adopted on a calendar year basis for the OPPS as well as a 0.9999 budget neutrality adjustment for the final CY 2022 5 percent cap on wage index decreases, requiring application of the 5 percent cap on CY 2021 wages, to ensure that this transition wage index is implemented in a budget neutral manner, consistent with the proposed FY 2022 IPPS wage index policy (86 FR 45552).

As a result of these finalized policies, the OPD fee schedule increase factor for the CY 2022 OPPS is 2.0 percent (which reflects the 2.7 percent final estimate of the hospital inpatient market basket percentage increase with a 0.7 percentage point MFP adjustment). For CY 2022, we are using a conversion factor of $84.177 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the OPD fee schedule increase factor of 2.0 percent for CY 2022, the required wage index budget neutrality adjustment of 1.0000, and the adjustment of −0.32 percentage point of projected OPPS spending for the difference in pass-through spending that results in a conversion factor for CY 2022 of $84.177.

C. Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B. of the CY 2022 OPPS/ASC proposed rule (86 FR 42048 through 42049).

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We proposed to continue this policy for the CY 2022 OPPS. We referred readers to section II.H. of the CY 2022 OPPS/ASC proposed rule (86 FR 42056 through 42058) for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital. We did not receive any public comments on this proposal. Accordingly, for the reasons discussed above and in the CY 2022 OPPS/ASC proposed rule, we are finalizing our proposal, without modification, to continue this policy for the CY 2022 OPPS.

As discussed in the claims accounting narrative included with the supporting documentation for this final rule with comment period (which is available via the internet on the CMS website), for estimating APC costs, we are standardizing 60 percent of estimated claims costs for geographic area wage variation using the same FY 2022 pre-reclassified wage index that we use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule

with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For 2022, we proposed to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We referred readers to the FY 2011 through FY 2021 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of ''frontier States'' as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: for FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 through 53370; for FY 2014, 78 FR 50590 through 50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; for FY 2017, 81 FR 56922; for FY 2018, 82 FR 38142; for FY 2019, 83 FR 41380; for FY 2020, 84 FR 42312; and for FY 2021, 85 FR 58765. We did not receive any public comments on this proposal. Accordingly, for the reasons discussed above and in the CY 2022 OPPS/ASC proposed rule, we are finalizing our proposal, without modification, to continue to implement the frontier State floor under the OPPS in the same manner as we have since CY 2011.

In addition to the changes required by the Affordable Care Act, we noted in the CY 2022 OPPS/ASC proposed rule (86 FR 42050) that the proposed FY 2022 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and an adjustment to the wage index for certain low wage index hospitals to help address wage index disparities between low and high wage index hospitals. In addition, we noted that in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25405 through 25407), we proposed to implement section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) which reinstates the imputed floor wage index adjustment under the IPPS for hospitals in all-urban states effective for discharges on or after October 1, 2021 (FY 2022) using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. Specifically, section 1886(d)(3)(E)(iv)(I) and (II) of the Act, as added by section 9831 of the American Rescue Plan Act, provides that for discharges occurring on or after October 1, 2021, the area wage index applicable under the IPPS 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. We further noted in the FY 2022 IPPS/LTCH PPS proposed rule that, given the recent enactment of section 9831 of Public Law 117–2 on March 11, 2021, there was not sufficient time available to incorporate the changes required by this statutory provision (the reinstatement of the imputed floor wage index) into the calculation of the IPPS provider wage index for the FY 2022 IPPS/LTCH PPS proposed rule, and we stated that we would include the imputed floor wage index adjustment in the calculation of the IPPS provider wage index in the FY 2022 IPPS/LTCH PPS final rule. We noted that CMS posted, concurrent with the issuance of the FY 2022 IPPS/LTCH proposed rule, estimated imputed floor values by state in a separate data file on the FY 2022 IPPS Proposed Rule web page on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. In addition, we stated in the FY 2022 IPPS/LTCH PPS proposed rule that, based on data available for the FY 2022 IPPS/LTCH PPS proposed rule, the following States would be all-urban States as defined in section 1886(d)(3)(E)(iv)(IV) of the Act, and thus hospitals in such States would be eligible to receive an increase in their wage index due to application of the imputed floor for FY 2022: New Jersey, Rhode Island, Delaware, Connecticut, and Washington, DC. We referred readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25396 through 25417) for a detailed discussion of all proposed changes to the FY 2022 IPPS wage indexes.

A summary of the comments we received regarding the rural floor and the imputed floor for all-urban states and our responses to those comments appear below:

Comment: Some commenters expressed their support for the application of the rural floor policy which included support for the continued exclusion of the wage data of hospitals that have reclassified as rural under § 412.103 when calculating the wage index for the rural floor.

Response: We appreciate the commenters' support for the application of the rural floor policy.

Comment: Some commenters opposed the continued application of a nationwide rural floor budget neutrality adjustment, noting that the policy does nothing more than benefit a few hospitals and exacerbate a downward spiral of the wage index for low wage index hospitals.

Response: We appreciate the commenters' concerns about application of the nationwide rural floor budget neutrality policy. However, as stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56920), for discharges occurring on or after October 1, 2010, for purposes of applying the rural floor, section 3141 of the Affordable Care Act replaced the statewide budget neutrality adjustment policy with the national budget neutrality adjustment policy that was in place during FY 2008. That is, section 3141 required that budget neutrality for the rural floor be applied ''through a uniform, national adjustment to the area wage index'' instead of within each State beginning in FY 2011 (75 FR 50160).

We continue to believe it is reasonable and appropriate to continue the current policy of applying budget neutrality for the rural floor under the OPPS on a national basis, consistent with the IPPS. We believe that hospital inpatient and outpatient departments are subject to the same labor cost environment, and therefore, the wage index and any applicable wage index adjustments (including the rural floor and rural floor budget neutrality) should be applied in the same manner under the IPPS and OPPS. Furthermore, we believe that applying the rural floor and rural floor budget neutrality in the same manner under the IPPS and OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In addition, we believe the application of different wage indexes and wage index adjustments under the IPPS and OPPS would add a level of administrative complexity that is overly burdensome and unnecessary. Therefore, we are

continuing the current policy of applying budget neutrality for the rural floor under the OPPS on a national basis, consistent with the IPPS.

Comment: Some commenters supported the proposed implementation of the imputed floor wage index policy. However, one commenter opposed the reinstatement of the imputed floor, stating that it exacerbates wage index disparities, but acknowledged that the proposal was in accordance with legislation enacted by Congress. This commenter requested CMS include details by state of the effects of the imputed floor. Commenters both in support and in opposition of the imputed floor policy applauded its implementation without the application of budget neutrality, per section 9831 of the American Rescue Plan Act of 2021. A commenter specifically concurred with CMS' interpretation that the definition of an all-urban state according to section 9831 of the American Rescue Plan Act of 2021 is one in which no hospital receives the rural area wage index.

Response: We appreciate the commenters' support of the proposed implementation of the imputed floor policy, which we note has been finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45176 through 45178). Responding to the commenter opposed to this policy, we underscore that, as the commenter itself pointed out, the imputed floor has been reinstated by statute in section 9831 of the American Rescue Plan Act of 2021. We believe that it is appropriate to apply the imputed floor policy in the OPPS in the same manner as under the IPPS, given the inseparable, subordinate status of the HOPD within the hospital overall.

In response to the commenter's request for details by state of the effects of the imputed floor, we direct the commenter to the data file that CMS posted concurrent with the FY 2022 IPPS/LTCH PPS proposed rule with estimated imputed floor value by state at *https://www.cms.gov/files/zip/fy2022-ipps-nprm-imputed-state-floors.zip*. Finally, we note that section 9831 of the American Rescue Plan Act of 2021 excluded the imputed floor from the budget neutrality requirement under the IPPS (section 1886(d)(3)(E)(i) of the Act) but did not specify that the same budget neutral treatment also would apply under the OPPS. As a result, the changes related to the reinstatement of the imputed floor would be budget neutralized through the standard OPPS wage index budget neutrality adjustment, as discussed in section II.B. of this final rule with comment period.

For more information about the imputed floor required by section 1886(d)(3)(E)(iv) of the Act, we refer readers to the regulations at § 412.64(e)(1) and (4) and (h)(4) and (5), and the discussion in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45176 through 45178).

In the CY 2022 OPPS/ASC proposed rule (86 FR 42050), we noted that as discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) and in each subsequent IPPS/LTCH PPS final rule, including the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58755), the Office of Management and Budget (OMB) issued revisions to the labor market area delineations on February 28, 2013 (based on 2010 Decennial Census data) that included a number of significant changes, such as new Core Based Statistical Areas (CBSAs), urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart (OMB Bulletin 13–01). This bulletin can be found at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf*. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49985), for purposes of the IPPS, we adopted the use of the OMB statistical area delineations contained in OMB Bulletin No. 13–01, effective October 1, 2014. For purposes of the OPPS, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66826 through 66828), we adopted the use of the OMB statistical area delineations contained in OMB Bulletin No. 13–01, effective January 1, 2015, beginning with the CY 2015 OPPS wage indexes. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted revisions to statistical areas contained in OMB Bulletin No. 15–01, issued on July 15, 2015, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. For purposes of the OPPS, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79598), we adopted the revisions to the OMB statistical area delineations contained in OMB Bulletin No. 15–01, effective January 1, 2017, beginning with the CY 2017 OPPS wage indexes.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provided detailed information on the update to the statistical areas since July 15, 2015, and were based on the 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. For purposes of the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58863 through 58865), we adopted the updates set forth in OMB Bulletin No. 17–01, effective January 1, 2019, beginning with the CY 2019 wage index.

On April 10, 2018, OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. Typically, interim OMB bulletins (those issued between decennial censuses) have only contained minor modifications to labor market delineations. However, the April 10, 2018 OMB Bulletin No. 18–03 and the September 14, 2018 OMB Bulletin No. 18–04 included more modifications to the labor market areas than are typical for OMB bulletins issued between decennial censuses, including some new CBSAs, urban counties that became rural, rural counties that became urban, and some existing CBSAs that were split apart. In addition, some of these modifications had a number of downstream effects, such as reclassification changes. 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. For purposes of the OPPS, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85907 through 85908), we adopted the updates set forth in OMB Bulletin No. 18–04 effective January 1, 2021, beginning with the CY 2021 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 18–04, we refer readers to the CY 2021 OPPS/ASC final rule with comment period.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the updates to statistical areas since September 14, 2018, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2017 and July 1, 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, one new component of an existing Combined Statistical Area and changes to New England City and Town Area (NECTA) delineations. As we stated in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25397), after reviewing OMB Bulletin No. 20–01, we determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the Medicare IPPS wage index for FY 2022. Specifically, the updates consisted of changes to NECTA delineations and the creation of a new Micropolitan Statistical Area, which was then added as a new component to an existing Micropolitan Statistical Area. The Medicare wage index does not utilize NECTA definitions, and, as most recently discussed in FY 2021 IPPS/LTCH PPS final rule (85 FR 58746), we include hospitals located in Micropolitan Statistical areas in each State's rural wage index. Therefore, consistent with our discussion in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45164), while we are adopting the updates set forth in OMB Bulletin No. 20–01 consistent with our general policy of adopting OMB delineation updates, we note that specific OPPS wage index updates would not be necessary for CY 2022 as a result of adopting these OMB updates. In other words, these OMB updates would not affect any hospital's geographic area for purposes of the OPPS wage index calculation for CY 2022.

For CY 2022, we are continuing 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, 18–04, and 20–01, although as noted above the latter Bulletin did not require any wage area updates.

We noted in the CY 2022 OPPS/ASC proposed rule (86 FR 42051) that, in connection with our adoption in FY 2021 of the updates in OMB Bulletin 18–04, we adopted a policy to place a 5 percent cap, for FY 2021, 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. We referred the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58753 through 58755) for a complete discussion of this transition. As finalized in the FY 2021 IPPS/LTCH PPS final rule, this transition was set to expire at the end of FY 2021. However, as discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25397), given the unprecedented nature of the ongoing COVID–19 PHE, we sought comment in the FY 2022 IPPS/LTCH PPS proposed rule on whether it would be appropriate to continue to apply a transition for the FY 2022 IPPS wage index for hospitals negatively impacted by our adoption of the updates in OMB Bulletin 18–04. For example, we stated that such an extended transition could potentially take the form of holding the FY 2022 IPPS wage index for those hospitals harmless from any reduction relative to their FY 2021 wage index. We further stated that if we were to apply a transition to the FY 2022 IPPS wage index for hospitals negatively impacted by our adoption of the updates in OMB Bulletin 18–04, we also sought comment on making this transition budget neutral under the IPPS, as is our usual practice, in the same manner that the FY 2021 IPPS wage index transition was made budget neutral as discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58755).

A summary of the comments we received regarding a wage index transition policy for 2022 as described above, and our responses to those comments, appear below:

Comment: We received multiple comments strongly recommending CMS extend a transition policy similar to that implemented in FY 2020 and FY 2021 in the IPPS. Multiple commenters, citing the severity and continuing impact of changes related to the OMB updates, the low wage index policy, and the lingering financial burden caused by the COVID–19 PHE, urged CMS to add an additional year of transition for both inpatient hospital and outpatient hospital providers, applied in a budget neutral manner. These commenters stated that given the wide-ranging factors impacting wage index values, it would not be equitable to limit the transition adjustment only to the effects of the revised labor market delineations. The commenters requested the transition be implemented more broadly to all hospitals experiencing large declines in wage index values. Many of these commenters recommended CMS consider making a permanent 5 percent maximum reduction policy to protect hospitals from large year-to-year variations in wage index values as a means to reduce overall volatility.

Multiple commenters requested that CMS extend a hold harmless policy for all hospitals negatively affected by CMS' adoption of revised delineations until OMB releases further revisions predicated on the results of the 2020 decennial census. A commenter recommended a hold-harmless transition be applied specifically to hospitals in CBSAs that were negatively affected by the FY 2021 adoption of revised CBSAs, citing specific CBSAs they believed warranted an additional transition adjustment.

Multiple commenters, while supporting some form of transition adjustment for negatively affected hospitals, requested any such adjustment be made in a non-budget neutral manner. These commenters expressed their preference that any such adjustment should not come at the expense of the providers themselves. Some commenters stated that such a budget neutrality adjustment would disadvantage providers who have increased their wage index values due to a variety of factors.

Response: We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45164 through 45165) for a detailed discussion of the wage index transition policy finalized for the FY 2022 IPPS wage index and for responses to these and other comments relating to the wage index transition policy.

As we noted, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45164 through 45165), we finalized a wage index transition policy for the FY 2022 IPPS wage index. Specifically, for hospitals that received the transition in FY 2021, we are continuing a wage index transition for FY 2022 under which we will apply a 5 percent cap on any decrease in the hospital's wage index compared to its wage index for 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 (86 FR 45164). We stated that, as discussed in the FY 2021 IPPS/LTCH final rule, we believe applying a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year is an appropriate transition as it provides predictability in payment levels from FY 2021 to the upcoming FY 2022 as well as effectively mitigating any significant decreases in the wage index for FY 2022 (86 FR 45164). We considered and responded to comments requesting that we apply the transition adjustment in FY 2022 to all hospitals with significant reductions in wage index values (not just those that received the transition adjustment in FY 2021), as well as comments recommending a 5-percent cap become a permanent policy for future fiscal years (86 FR 45164 through 45165). In addition, we considered and responded to comments recommending we not apply the transition in a budget neutral manner (86 FR 45165). We stated that

for FY 2022, similar to FY 2021, we are applying a budget neutrality adjustment to the standardized amount so that our transition, as previously described, is implemented in a budget neutral manner under our authority in section 1886(d)(5)(I) of the Act (86 FR 45165).

In the CY 2022 OPPS/ASC proposed rule (86 FR 42051 through 42052), we proposed to use the FY 2022 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2022. Therefore, as we stated in the CY 2022 OPPS/ASC proposed rule (86 FR 42052), any adjustments for the FY 2022 IPPS post-reclassified wage index, including without limitation any wage index transition policy that may be applied, would be reflected in the final CY 2022 OPPS wage index beginning on January 1, 2022. We continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. For this reason, as discussed later in this section, we are finalizing our proposal to use the FY 2022 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2022, which will include the wage index transition policy discussed previously.

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the IPPS and OPPS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: *https://www.census.gov/geo/reference/county-changes.html* (which, as of May 6, 2019, migrated to: *https://www.census.gov/programs-surveys/geography.html*). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of crosswalking counties to CBSAs for the OPPS wage index, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes. For CY 2022, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

We proposed to use the FY 2022 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2022. Therefore, we stated that any adjustments for the FY 2022 IPPS post-reclassified wage index, including, but not limited to, the imputed floor adjustment and any transition that may be applied (as discussed previously), would be reflected in the final CY 2022 OPPS wage index beginning on January 1, 2022. (We referred readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25396 through 25417) and the proposed FY 2022 hospital wage index files posted on the CMS website.) With regard to budget neutrality for the CY 2022 OPPS wage index, we referred readers to section II.B. of the CY 2022 OPPS/ASC proposed rule (86 FR 42048 through 42049). We stated that we continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

We refer readers to the discussion of comments on the wage index transition policy for 2022, and our responses to those comments, earlier in this section. We did not receive any additional comments on this proposal and are finalizing it without modification.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index adjustments. In the CY 2022 OPPS/ASC proposed rule, we proposed to continue this policy for CY 2022, and included a brief summary of the major proposed FY 2022 IPPS wage index policies and adjustments that we proposed to apply to these hospitals under the OPPS for CY 2022. which we have summarized below. We referred readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25396 through 25417) for a detailed discussion of the proposed changes to the FY 2022 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that would apply if the hospital were paid under the IPPS. For CY 2022, we proposed to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the outmigration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA). Furthermore, we proposed that the wage index that would apply for CY 2022 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and any adjustments applied to the IPPS wage index to address wage index disparities. In addition, the wage index that would apply to non-IPPS hospitals paid under the OPPS would include any transition we may finalize for the FY 2022 IPPS wage index as discussed previously.

We did not receive any comments on these proposals and are finalizing them without modification.

For CMHCs, for CY 2022, we proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. Furthermore, we proposed that the wage index that would apply to CMHCs for CY 2022 would continue to include the rural floor adjustment and any adjustments applied to the IPPS wage index to address wage index disparities. In addition, the wage index that would apply to CMHCs would include any transition we may finalize for the FY 2022 IPPS wage index as discussed above. Also, we proposed that the wage index that would apply to CMHCs would not include the outmigration adjustment because that

adjustment only applies to hospitals. We did not receive any comments on these proposals and are finalizing them without modification.

Table 4A associated with the FY 2022 IPPS/LTCH PPS final rule (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) identifies counties eligible for the out-migration adjustment. Table 2 associated with the FY 2022 IPPS/LTCH PPS final rule (available for download via the website above) identifies IPPS hospitals that receive the out-migration adjustment for FY 2022. We are including the outmigration adjustment information from Table 2 associated with the FY 2022 IPPS/LTCH PPS final rule as Addendum L to the CY 2022 OPPS/ASC final rule with the addition of non-IPPS hospitals that will receive the section 505 outmigration adjustment under the CY 2022 OPPS/ASC final rule. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index*. At this link, readers will find a link to the final FY 2022 IPPS wage index tables and Addendum L.

D. Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, we use overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the statewide average default CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. We also use the statewide average default CCRs to determine payments for hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11).

We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers to the CY 2022 OPPS final rule Claims Accounting Narrative that is posted on our website. We proposed to calculate the default ratios for CY 2022 using cost report data from the same set of cost reports we originally used in the CY 2021 OPPS ratesetting, consistent with the broader proposal regarding 2022 OPPS ratesetting discussed in section X.E. of the CY 2022 OPPS/ASC proposed rule (86 FR 42188 through 42190).

We did not receive any public comments on our proposal and are finalizing our proposal, without modification, to calculate the default ratios for CY 2022 using cost report data from the same set of cost reports we originally used in the CY 2021 OPPS ratesetting.

We no longer publish a table in the **Federal Register** containing the statewide average CCRs in the annual OPPS proposed rule and final rule with comment period. These CCRs with the upper limit will be available for download with each OPPS CY proposed rule and final rule on the CMS website. We refer readers to our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; click on the link on the left of the page titled ''Hospital Outpatient Regulations and Notices'' and then select the relevant regulation to download the statewide CCRs and upper limit in the Downloads section of the web page.

E. Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2022

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Public Law 105–33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2021. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For CY 2022, we proposed to continue the current policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy.

Comment: One commenter requested that CMS make the 7.1 percent rural adjustment permanent. The commenter appreciated the policy that CMS

adopted in CY 2019 and reaffirmed in CY 2020 where we stated that the 7.1 percent rural adjustment would continue to be in place until our data support establishing a different rural adjustment percentage. However, the commenter believes that this policy still does not provide enough certainty for rural SCHs and EACHs to know whether they should take into account the rural SCH adjustment when attempting to calculate expected revenues for their hospital budgets.

Response: We thank the commenter for their input. We believe that our current policy, which states that the 7.1 percent payment adjustment for rural SCHs and EACHs will remain in effect until our data show that a different percentage for the rural payment adjustment is necessary, provides sufficient budget predictability for rural SCHs and EACHs. Providers would receive notice in a proposed rule and have the opportunity to provide comments before any changes to the rural adjustment percentage would be implemented.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to continue the current policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the passthrough payment policy, and items paid at charges reduced to costs.

F. Payment Adjustment for Certain Cancer Hospitals for CY 2022

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), the Congress added section 1833(t)(7), ''Transitional Adjustment to Limit Decline in Payment,'' to the Act, which requires the Secretary to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (these hospitals are often referred to under this policy as ''held harmless'' and their payments are often referred to as ''hold harmless'' payments).

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is the product of the hospital's reasonable costs for covered outpatient services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount'' and the determination of the base PCR are defined at § 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. Table 5 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2021.

TABLE 5: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT PAYMENT-TO-COST RATIOS (PCRs), CY 2012 THROUGH CY 2021

Calendar Year	Target PCR
2012	0.91
2013	0.91
2014	0.90
2015	0.90
2016	0.92
2017	0.91
2018	0.88
2019	0.88
2020	0.89
2021	0.89

2. Policy for CY 2022

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying § 419.43(i) (that is, the payment adjustment for certain cancer hospitals) for services furnished on or after January 1, 2018, the target PCR adjustment be reduced by 1.0 percentage point less than what would otherwise apply. Section 16002(b) also provides that, in addition to the percentage reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services described under section 1833(t)(21)(C) of the Act for hospitals that are not cancer hospitals described under section 1886(d)(1)(B)(v) of the Act. Further, in making any budget neutrality adjustment under section 1833(t) of the Act, the Secretary shall not take into account the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act.

We proposed to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals, using the most recent submitted or settled cost report data that were available at the time of the development of the proposed rule, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act. We did not propose an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2022.

Under our established policy, to calculate the proposed CY 2022 target PCR, we would use the same extract of cost report data from HCRIS used to estimate costs for the CY 2022 OPPS which would be the most recently available hospital cost reports which, in most cases, would be from CY 2020. However, as discussed in section II.A.1.a of the CY 2022 OPPS/ASC proposed rule, given our concerns with CY 2020 claims data as a result of the PHE, we believe a target PCR based on CY 2020 claims and the most recently available cost reports may provide a less accurate estimation of cancer hospital PCRs and non-cancer hospital PCRs than the data used for the CY 2021 rulemaking cycle. Therefore, for CY 2022, we proposed to continue to use the CY 2021 target PCR of 0.89. This proposed CY 2022 target PCR of 0.89 includes the 1.0-percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2022. For a description of the CY 2021 target PCR calculation, we refer readers to the CY 2021 OPPS/ASC final rule with comment period (84 FR 85912 through 85914).

We did not receive any public comments on our proposal and we are finalizing our proposal to continue to use the CY 2021 target PCR of 0.89 for the 11 specified cancer hospitals for CY 2022 without modification.

Table 6 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2022, due to the cancer hospital payment adjustment policy. The actual amount of the CY 2022 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2022 payments and costs. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

BILLING CODE 4120–01–P

TABLE 6: Estimated CY 2022 Hospital-Specific Payment Adjustment For Cancer Hospitals To Be Provided At Cost Report Settlement

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2022 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	39.6%
050660	USC Norris Cancer Hospital	31.7%
100079	Sylvester Comprehensive Cancer Center	16.5%
100271	H. Lee Moffitt Cancer Center & Research Institute	20.8%
220162	Dana-Farber Cancer Institute	34.7%
330154	Memorial Sloan-Kettering Cancer Center	38.1%
330354	Roswell Park Cancer Institute	14.0%
360242	James Cancer Hospital & Solove Research Institute	16.4%
390196	Fox Chase Cancer Center	11.2%
450076	M.D. Anderson Cancer Center	51.4%
500138	Seattle Cancer Care Alliance	46.5%

BILLING CODE 4120–01–C

G. Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars). In CY 2021, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $5,300 (the fixed-dollar amount threshold) (85 FR 85914 through 85916). If the cost of a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Using CY 2019 claims available for this final rule with comment period, we estimate that we paid approximately 0.89 percent of the total aggregated OPPS payments in outliers for CY 2019. Therefore, for CY 2019, we estimate that we paid 0.11 percentage points below the CY 2019 outlier target of 1.0 percent of total aggregated OPPS payments.

For this final rule with comment period, using CY 2019 claims data and CY 2021 payment rates, we estimate that the aggregate outlier payments for CY 2021 would be approximately 1.07 percent of the total CY 2021 OPPS payments. We provide estimated CY 2021 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts—Provider-Specific Data file on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

2. Outlier Calculation for CY 2022

For CY 2022, we proposed to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We proposed that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments), would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. We proposed to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under APC 5853 (Partial Hospitalization for CMHCs), exceeds 3.40 times the payment rate for

proposed APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC 5853 payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of the CY 2022 OPPS/ASC proposed rule.

To ensure that the estimated CY 2022 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus $6,100.

We calculated the proposed fixed-dollar threshold of $6,100 using the standard methodology most recently used for CY 2021 (85 FR 85914 through 85916). For purposes of estimating outlier payments for the CY 2022 OPPS/ASC proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2020 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we generally use to model each OPPS update lag by 2 years. However, as discussed in section X.E. of the CY 2022 OPPS/ASC proposed rule, we proposed to use CY 2019 claims in establishing the CY 2022 OPPS.

In order to estimate the CY 2022 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2019 claims using the same inflation factor of 1.20469 that we used to estimate the IPPS fixed-loss cost threshold for the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25718). We used an inflation factor of 1.13218 to estimate CY 2021 charges from the CY 2019 charges reported on CY 2019 claims, applying the charge inflation factor for two years, to estimate CY 2021 hospital outlier payments. The methodology for determining this charge inflation factor is discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59037 through 59040). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65844 through 65846), we believe that the use of these charge inflation factors is appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we proposed to apply the same CCR inflation adjustment factor that we proposed to apply for the FY 2022 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2022 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2022, we proposed to apply an adjustment factor of 0.94964 (or 0.974495 * 0.974495) to the CCRs that were in the April 2020 OPSF to trend them forward from CY 2020 to CY 2022. We note that we proposed to use the April 2020 OPSF to address concerns regarding the impact of the PHE on data used in OPPS ratesetting, as discussed in section X.E. of the CY 2022 OPPS/ASC proposed rule. The methodology for calculating the proposed adjustment is discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25717 through 25719).

To model hospital outlier payments for the CY 2022 OPPS/ASC proposed rule, we applied the overall CCRs from the April 2020 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.94964 to approximate CY 2022 CCRs) to charges on CY 2019 claims that were adjusted (using the proposed charge inflation factor of 1.20469 to approximate CY 2022 charges). We note that the additional year in the charge inflation factor and CCR inflation factors is a result of the use of claims and OPSF data from a year earlier than the year that we would typically use in a standard ratesetting cycle. We simulated aggregated CY 2021 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2021 OPPS payments. We estimated that a proposed fixed-dollar threshold of $6,100, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we proposed that, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate for APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that will apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we proposed to continue the policy that we implemented in CY 2010 that the hospitals' costs will be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XIV. of the CY 2022 OPPS/ASC proposed rule.

Comment: One commenter recommended that, in light of the PHE, CMS should not update the OPPS outlier fixed-dollar threshold at a time when hospitals are struggling financially.

Response: We maintain the target outlier percentage of 1.0 percent of estimated aggregate total payments under the OPPS and have a fixed-dollar threshold so that OPPS outlier payments are made only when the hospital would experience a significant loss for furnishing a particular service. We continue to believe that the 1.0 percent OPPS outlier spending target appropriately mitigates the financial risk associated with exceptionally costly or complex cases. In addition, in a budget neutral system any spending for OPPS outliers would require a corresponding reduction to all other OPPS payments, which would have a universal impact on hospitals because every OPPS payment would be reduced. The fixed-dollar outlier threshold is specifically developed in order to best estimate aggregate outlier payments of 1.0 percent of the OPPS and ensure that outlier payments are directed towards the high cost and complex procedures associated with potential financial risk. Failing to update this outlier threshold would systemically underestimate the

amount of OPPS outlier payments and result in OPPS outlier payments in excess of 1.0 percent of aggregate OPPS payments.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS and to use our established methodology to set the OPPS outlier fixed-dollar loss threshold for CY 2022.

3. Final Outlier Calculation

Historically, we have used updated data for the outlier fixed-dollar threshold calculation for the final rule. However, as discussed in section X.E. of the CY 2022 OPPS/ASC proposed rule (86 FR 42188 through 42190) claims and other data that we would typically have used as part of our ratesetting process would have been affected by the PHE. As a result, we proposed to use CY 2019 OPPS claims as part of the CY 2022 OPPS ratesetting process. For purposes of estimating the outlier threshold, we are finalizing our proposal to apply the same CCR inflation adjustment factor that we finalized to apply for the FY 2022 IPPS outlier calculation to the CCRs used to simulate the final CY 2022 OPPS outlier payments to determine the fixed-dollar threshold. As discussed in the FY 2022 IPPS/LTCH PPS final rule with comment period (86 FR 45537 through 45543), there are some changes to the typical charge and CCR inflation factors we would use for outlier estimating purposes as a result of the proposed and final policy to use data prior to the PHE. Ordinarily, we would use updated CCRs of the OPSF and apply an adjustment factor to adjust the CCRs from the most recent update of OPSF. However, as discussed previously, we believe the most recent CCRs in the OPSF may be significantly impacted by the PHE. As a result, and similar to the proposed use of CY 2019 claims in CY 2022 OPPS ratesetting more broadly, we proposed to use OPSF CCRs from the April 2020 OPSF for CY 2022 outlier estimation purposes. The claims and OPSF data are not the most updated data available and therefore to properly update them for the prospective year—CY 2022—we needed to apply an additional year of CCRs and charge inflation. For CY 2022, we are applying the overall CCRs from the April 2020 OPSF file (using the CCR inflation adjustment factor of 0.94964 to approximate CY 2021 CCRs) to charges on CY 2019 claims that were adjusted using a charge inflation factor of 1.20469 to approximate CY 2022 charges. These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-loss cost threshold for the FY 2022 IPPS/LTCH PPS final rule (86 FR 45537 through 45543). We simulate aggregate CY 2022 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple-threshold constant and assuming that outlier payments will continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until total outlier payments equal 1.0 percent of aggregated estimated total CY 2022 OPPS payments. We estimate that a fixed-dollar amount threshold of $6,175 combined with the multiplier threshold of 1.75 times the APC payment rate, will allocate the 1.0 percent of aggregated total OPPS payments to outlier payments. For CY 2022, we are finalizing a multiplier threshold of 1.75 times the APC payment rate and a fixed-dollar amount threshold of $6,175.

For CMHCs, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times APC 5853.

H. Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this final rule with comment period, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this final rule with comment period and the relative payment weight determined under section II.A. of this final rule with comment period. Therefore, the national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period (which is available via the internet on the CMS website) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this final rule with comment period (which is available via the internet on the CMS website) was calculated by multiplying the final CY 2022 scaled weight for the APC by the CY 2022 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIV. of this final rule with comment period.

We demonstrate the steps used to determine the APC payments that will be made in a CY under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''Q4'', ''R'', ''S'', ''T'', ''U'', or ''V'' (as defined in Addendum D1 to the proposed rule, which is available via the internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to the proposed rule (which are available via the internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced

national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.9804 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements to receive the full CY 2022 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

X = .60 * (national unadjusted payment rate).

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area would reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2022 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) ''Lugar'' hospitals, and reclassifications under section 1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. We are continuing to apply for the CY 2022 OPPS wage index any adjustments for the FY 2022 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment, a wage index floor of 1.00 in frontier states, in accordance with section 10324 of the Affordable Care Act of 2010, and an adjustment to the wage index for certain low wage index hospitals. For further discussion of the wage index we are applying for the CY 2022 OPPS, we refer readers to section II.C. of this final rule with comment period.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Pub. L. 108–173. Addendum L to this final rule with comment period (which is available via the internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the final FY 2022 IPPS wage index, which are listed in Table 2 associated with the FY 2022 IPPS/LTCH PPS final rule and available via the internet on the CMS website at: *http://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 2022 IPPS Final Rule Home Page'' and select ''FY 2022 Final Rule Tables.'') This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = .60 * (national unadjusted payment rate) * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = .40 * (national unadjusted payment rate).

Adjusted Medicare Payment = $Y + X_a$.

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined previously. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The CY 2022 full national unadjusted payment rate for APC 5071 is $635.54. The proposed reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $623.08. This proposed reduced rate is calculated by multiplying the reporting ratio of 0.9804 by the full unadjusted payment rate for APC 5071.

The FY 2022 wage index for a provider located in CBSA 35614 in New York, which includes the proposed adoption of IPPS 2022 wage index policies, is 1.3427. The labor-related portion of the proposed full national unadjusted payment is approximately $512.00 (.60 * $635.54 * 1.3427). The labor-related portion of the proposed reduced national unadjusted payment is approximately $501.97 (.60 * $623.08 * 1.3427). The nonlabor-related portion of the proposed full national unadjusted payment is approximately $254.22 (.40 * $635.54). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately $249.23 (.40 * $623.08). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $766.22 ($512.00 + $254.22). The sum of the portions of the proposed reduced national adjusted payment is approximately $751.20 ($501.97 + $249.23).

We did not receive any public comments on these steps under the methodology that we included in the proposed rule to determine the APC payments for CY 2022. Therefore, we are using the steps in the methodology specified above, as we proposed, to demonstrate the calculation of the final

CY 2021 OPPS payments using the same parameters.

I. Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in CYs thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. For a discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011 we refer readers to section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

2. OPPS Copayment Policy

For CY 2022, we proposed to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we proposed to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2022 are included in Addenda A and B to the proposed rule (which are available via the internet on the CMS website).

As discussed in section XIV.E. of the CY 2022 OPPS/ASC proposed rule and this final rule with comment period, for CY 2022, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates, due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).
- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116–260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section

1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We refer readers to section X.B., ''Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests'' of this final rule with comment period for the full discussion of this policy.

Comment: One commenter requested that CMS waive the patient coinsurance and deductible for Biomechanical Computed Tomography (BCT) analysis, CPT 0554T to 0558T under the Medicare preventive services benefit 42 CFR 410.152(l)(6). The commenter stated that these codes are considered preventive services for diagnostic screening of osteoporosis and that Change Request (CR) 11392 directed contractors to apply the same rules applied to CPT code 77078 (Computed tomography, bone mineral density study, 1 or more sites, axial skeleton (for example, hips, pelvis, spine)) to these BCT codes.

Response: We disagree with the commenter that the BCT codes are not subject to coinsurance and the Part B deductible at this time. The service described by CPT code 77078 meets the National Coverage Determination (NCD) process for preventive services coverage and subject to its coinsurance and deductible waiver. However, the USPSTF has not changed its current recommendation for bone measurement testing (available here: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/osteoporosis-screening#fullrecommendationstart*) since 2018. These new BCT codes became effective July 1, 2019, and the services described by these codes are not specifically included in the USPSTF grade B recommendation. Therefore, they do not meet requirements to have beneficiary coinsurance and deductible waived. We note that CMS may add preventive services coverage through the National Coverage Determination (NCD) process if the service meets all of the following criteria: Reasonable and necessary for prevention or early detection of illness or disability, USPSTF recommended with grade A or B, and appropriate for individuals entitled to benefits under Part A or enrolled under Medicare Part B. In the event that the USPSTF updates its recommendation for bone measurement testing to specifically include these services described by the new BCT codes, CMS would reevaluate whether to apply the coinsurance and deductible waiver.

3. Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 5071, $127.11 is approximately 20 percent of the full national unadjusted payment rate of $635.54. For APCs with only a minimum unadjusted copayment in Addenda A and B to the CY 2022 OPPS/ASC proposed rule (which are available via the internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of the CY 2022 OPPS/ASC proposed rule. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H. of the CY 2022 OPPS/ASC proposed rule.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this final rule with comment period, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B.*

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B.*

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.9804.

The unadjusted copayments for services payable under the OPPS that will be effective January 1, 2022 are shown in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website). We note that the national unadjusted payment rates and copayment rates shown in Addenda A and B to this final rule with comment period reflect the CY 2022 OPD fee schedule increase factor discussed in section II.B. of this final rule with comment period.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on HOPD claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the American Medical Association (AMA), and consists of Category I, II, and III CPT codes. Level II, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alphanumeric codes), which are used primarily to identify drugs, devices, ambulance services, durable medical equipment, orthotics, prosthetics, supplies, temporary surgical

procedures, and medical services not described by CPT codes.

CPT codes are established by the AMA and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA (via their website) while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes and makes the codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe the items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes, status indicators, and APC assignments through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. Those items, procedures, or services not exclusively paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not. In section XI. ''CY 2022 OPPS Payment Status and Comment Indicators'' of this final rule with comment period, we discuss the various status indicators used under the OPPS. We also provide a complete list of status indicators and their definitions in Addendum D1 to this final rule with comment period.

1. HCPCS Codes That Were Effective April 1, 2021 for Which We Solicited Public Comments in the CY 2022 OPPS/ASC Proposed Rule

For the April 2021 update, 26 new HCPCS codes were established and made effective on April 1, 2021. These codes and their long descriptors were included in Table 5 of the proposed rule and are now listed in Table 7 of this final rule with comment period. Through the April 2021 OPPS quarterly update CR (Transmittal 10666, Change Request 12175, dated March 8, 2021), we recognized several new HCPCS codes for separate payment under the OPPS. In the CY 2022 OPPS/ASC proposed rule, we solicited public comments on the proposed APC and status indicator assignments for the codes which were listed in Table 5 of this CY 2022 OPPS/ASC proposed rule with comment period.

We did not receive any public comments on the proposed OPPS APC and SI assignments for the new Level II HCPCS codes implemented in April 2021. Therefore, we are finalizing the proposed APC and SI assignments for these codes, as indicated in Table 7.

The status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this final rule with comment period. In addition, the complete list of status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this final rule with comment period. These new codes that were effective April 1, 2021 were assigned to comment indicator ''NP'' in Addendum B to the CY 2022 OPPS/ASC proposed rule to indicate that the codes were assigned to an interim APC assignment and that comments would be accepted on their interim APC assignments. Also, the complete list of comment indicators and definitions used under the OPPS can be found in Addendum D2 to this final rule with comment period. We note that OPPS Addendum B, Addendum D1, and Addendum D2 are available via the internet on the CMS website.

BILLING CODE 4120–01–P

TABLE 7: NEW HCPCS CODES EFFECTIVE APRIL 1, 2021

CY 2021 HCPCS Code	CY 2022 HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 SI	Final CY 2022 APC
A9592	A9592	Copper cu-64, dotatate, diagnostic, 1 millicurie	G	9383
C9074	J0224	Injection, lumasiran, 0.5 mg	G	9407
C9776	C9776	Intraoperative near-infrared fluorescence imaging of major extra-hepatic bile duct(s) (e.g., cystic duct, common bile duct and common hepatic duct) with intravenous administration of indocyanine green (icg) (list separately in addition to code for primary procedure)	N	N/A
C9777	C9777*	Esophageal mucosal integrity testing by electrical impedance, transoral, includes esophagoscopy or esophagogastroduodenoscopy	J1	5303
G2020	G2020	Services for high intensity clinical services associated with the initial engagement and outreach of beneficiaries assigned to the sip component of the pcf model (do not bill with chronic care management codes)	A	N/A
G2172	G2172	All inclusive payment for services related to highly coordinated and integrated opioid use disorder (oud) treatment services furnished for the demonstration project	A	N/A
J1427	J1427	Injection, viltolarsen, 10 mg	G	9386
J1554	J1554	Injection, immune globulin (asceniv), 500 mg	G	9392
J7402	J7402	Mometasone furoate sinus implant, (sinuva), 10 micrograms	G	9346
J9037	J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	G	9384
J9349	J9349	Injection, tafasitamab-cxix, 2 mg	G	9385
K1013	K1013	Enema tube, any type, replacement only, each	Y	N/A
K1014	K1014	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control	Y	N/A
K1015	K1015	Foot, adductus positioning device, adjustable	Y	N/A
K1016	K1016	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve	Y	N/A
K1017	K1017	Monthly supplies for use of device coded at K1016	Y	N/A

CY 2021 HCPCS Code	CY 2022 HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 SI	Final CY 2022 APC
K1018	K1018	External upper limb tremor stimulator of the peripheral nerves of the wrist	Y	N/A
K1019	K1019	Monthly supplies for use of device coded at K1018	Y	N/A
K1020	K1020	Non-invasive vagus nerve stimulator	Y	N/A
Q2053	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9391
0242U	0242U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements	A	N/A
0243U	0243U	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia	Q4	N/A
0244U	0244U	Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single-nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-fixed paraffin embedded tumor tissue	A	N/A
0245U	0245U	Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage	A	N/A
0246U	0246U	Red blood cell antigen typing, DNA, genotyping of at least 16 blood groups with phenotype prediction of at least 51 red blood cell antigens	A	N/A
0247U	0247U	Obstetrics (preterm birth), insulin-like growth factor–binding protein 4 (IBP4), sex hormone–binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal	Q4	N/A

CY 2021 HCPCS Code	CY 2022 HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 SI	Final CY 2022 APC
		serum, combined with clinical data, reported as predictive-risk stratification for spontaneous		

*Effective January 1, 2022, the descriptor for HCPCS code C9777 has been revised to "Esophageal mucosal integrity testing by electrical impedance, transoral, includes esophagoscopy or esophagogastroduodenoscopy" to describe the service associated with performing both a MiVu test and an esophagoscopy or esophagogastroduodenoscopy test. When performed together, HOPDs should report only HCPCS code C9777 and not report a separate HCPCS code for the esophagoscopy or esophagogastroduodenoscopy.

2. HCPCS Codes That Were Effective July 1, 2021 for Which We Solicited Public Comments in the CY 2022 OPPS/ASC Proposed Rule

For the July 2021 update, 55 new codes were established and made effective July 1, 2021. The codes and long descriptors were listed in Table 6 of the proposed rule and are now also listed in Table 8 of this final rule with comment period. Through the July 2021 OPPS quarterly update CR (Transmittal 10825, Change Request 12316, dated June 11, 2021), we recognized several new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs. In the CY 2022 OPPS/ASC proposed rule, we solicited public comments on the proposed APC and status indicator assignments for the codes implemented on July 1, 2021, all of which are listed in Table 8.

We did not receive any public comments on the proposed OPPS APC and SI assignments for the new Level II HCPCS codes implemented in July 2021 and we are finalizing the proposed APC and SI assignments for these codes, as indicated in Table 8. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective October 1, 2021. Their replacement codes are listed in Table 8. The final payment rates for these codes can be found in Addendum B to this final rule with comment period.

The status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this final rule with comment period. The complete list of status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this final rule with comment period. These new codes that were effective July 1, 2021 were assigned to comment indicator ''NP'' in Addendum B to the CY 2022 OPPS/ASC proposed rule to indicate that the codes were assigned to an interim APC assignment and that comments would be accepted on their interim APC assignments. Also, the complete list of comment indicators and definitions used under the OPPS can be found in Addendum D2 to this final rule with comment period. We note that OPPS Addendum B, Addendum D1, and Addendum D2 are available via the internet on the CMS website.

TABLE 8: NEW HCPCS CODES EFFECTIVE JULY 1, 2021

CY 2021 HCPCS Code	CY 2022 HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 SI	Final CY 2022 APC
A9593	A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	G	9409
A9594	A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	G	9410
C1761	C1761	Catheter, transluminal intravascular lithotripsy, coronary	H	2033
C9075	J1426	Injection, casimersen, 10 mg	G	9412
C9076	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9413
C9077	J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414
C9078	J1448	Injection, trilaciclib, 1 mg	G	9415
C9079	J1305	Injection, evinacumab-dgnb, 5 mg	G	9416
C9080	J9247	Injection, melphalan flufenamide, 1mg	G	9417
C9778	C9778	Colpopexy, vaginal; minimally invasive extra-peritoneal approach (sacrospinous)	J1	5414
G0327	G0327	Colorectal cancer screening; blood-based biomarker	A	N/A
J0224	J0224	Injection, lumasiran, 0.5 mg	G	9407
J1951	J1951	Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg	K	9419
J7168	J7168	Prothrombin complex concentrate (human), kcentra, per i.u. of factor ix activity	K	9132
J9348	J9348	Injection, naxitamab-gqgk, 1 mg	G	9408

CY 2021 HCPCS Code	CY 2022 HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 SI	Final CY 2022 APC
J9353	J9353	Injection, margetuximab-cmkb, 5 mg	G	9418
Q5123	Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg	G	9411
0640T	0640T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition, interpretation and report, each flap or wound	M	N/A
0641T	0641T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition only, each flap or wound	T	5732
0642T	0642T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); interpretation and report only, each flap or wound	M	N/A
0643T	0643T	Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach	C	N/A
0644T	0644T	Transcatheter removal or debulking of intracardiac mass (eg, vegetations, thrombus) via suction (eg, vacuum, aspiration) device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed	J1	5192
0645T	0645T	Transcatheter implantation of coronary sinus reduction device including vascular access and closure, right heart catheterization, venous angiography, coronary sinus angiography, imaging guidance, and supervision and interpretation, when performed	E1	N/A
0646T	0646T	Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed	E1	N/A
0647T	0647T	Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report	J1	5302
0648T	0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content),	S	5523

CY 2021 HCPCS Code	CY 2022 HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 SI	Final CY 2022 APC
		including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session		
0649T	0649T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	N	N/A
0650T	0650T	Programming device evaluation (remote) of subcutaneous cardiac rhythm monitor system, with iterative adjustment of the implantable device to test the function of the device and select optimal permanently programmed values with analysis, review and report by a physician or other qualified health care professional	Q1	5741
0651T	0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report	T	5301
0652T	0652T	Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	T	5301
0653T	0653T	Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple	T	5301
0654T	0654T	Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter	J1	5302
0655T	0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging	J1	5374
0656T	0656T	Vertebral body tethering, anterior; up to 7 vertebral segments	C	N/A
0657T	0657T	Vertebral body tethering, anterior; 8 or more vertebral segments	C	N/A
0658T	0658T	Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma risk score	S	5733
0659T	0659T	Transcatheter intracoronary infusion of supersaturated oxygen in conjunction with	C	N/A

CY 2021 HCPCS Code	CY 2022 HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 SI	Final CY 2022 APC
		percutaneous coronary revascularization during acute myocardial infarction, including catheter placement, imaging guidance (eg, fluoroscopy), angiography, and radiologic supervision and interpretation		
0660T	0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach	E1	N/A
0661T	0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant	E1	N/A
0662T	0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	1520
0663T	0663T	Scalp cooling, mechanical; placement of device, monitoring, and removal of device (list separately in addition to code for primary procedure)	N	N/A
0664T	0664T	Donor hysterectomy (including cold preservation); open, from cadaver donor	E1	N/A
0665T	0665T	Donor hysterectomy (including cold preservation); open, from living donor	E1	N/A
0666T	0666T	Donor hysterectomy (including cold preservation); laparoscopic or robotic, from living donor	E1	N/A
0667T	0667T	Donor hysterectomy (including cold preservation); recipient uterus allograft transplantation from cadaver or living donor	E1	N/A
0668T	0668T	Backbench standard preparation of cadaver or living donor uterine allograft prior to transplantation, including dissection and removal of surrounding soft tissues and preparation of uterine vein(s) and uterine artery(ies), as necessary	E1	N/A
0669T	0669T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; venous anastomosis, each	E1	N/A
0670T	0670T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; arterial anastomosis, each	E1	N/A
0248U	0248U	Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug	A	N/A
0249U	0249U	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes,	Q4	N/A

CY 2021 HCPCS Code	CY 2022 HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 SI	Final CY 2022 APC
		includes laser capture microdissection, with algorithmic analysis and interpretative report		
0250U	0250U	Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes, interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and deletions, one amplification, and four translocations), microsatellite instability and tumor-mutation burden	A	N/A
0251U	0251U	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma	Q4	N/A
0252U	0252U	Fetal aneuploidy short tandem–repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy	A	N/A
0253U	0253U	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive)	A	N/A
0254U	0254U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy, per embryo tested	A	N/A

BILLING CODE 4120–01–C

3. October 2021 HCPCS Codes for Which We Are Soliciting Public Comments in the CY 2022 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new HCPCS codes that are effective October 1 in the final rule with comment period, thereby updating the OPPS for the following calendar year, as displayed in Table 7 of the CY 2022 OPPS/ASC proposed rule with comment period and reprinted as Table 9 of this final rule with comment period. These codes are released to the public through the October OPPS quarterly update CRs and via the CMS HCPCS website (for Level II HCPCS codes). For CY 2022, these codes are flagged with comment indicator ''NI'' in Addendum B to this OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. Specifically, the interim SI and APC assignments for codes flagged with comment indicator ''NI'' are open to public comment in this final rule with comment period, and we will respond to these public comments in the OPPS/ASC final rule with comment period for the next year's OPPS/ASC update.

In the CY 2022 OPPS/ASC proposed rule (86 FR 42068), we proposed to continue this process for CY 2022. Specifically, for CY 2022, we proposed to include in Addendum B to the CY 2022 OPPS/ASC final rule with comment period the new HCPCS codes effective October 1, 2021 that would be incorporated in the October 2021 OPPS quarterly update CR. Also, as stated above, the October 1, 2021 codes are flagged with comment indicator ''NI'' in Addendum B to this CY 2022 OPPS/

ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2022. We are inviting public comments on the interim SI and APC assignments for these codes, if applicable, that will be finalized in the CY 2023 OPPS/ASC final rule with comment period.

4. January 2022 HCPCS Codes

a. New Level II HCPCS Codes for Which We Are Soliciting Public Comments in This CY 2022 OPPS/ASC Final Rule With Comment Period

Consistent with past practice, we are soliciting comments on the new Level II HCPCS codes that will be effective January 1, 2022 of this final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2023 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O of the CY 2022 OPPS/ASC proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Consequently, for CY 2022, we proposed to include in Addendum B to this final rule with comment period the new Level II HCPCS codes effective January 1, 2022 that would be incorporated in the January 2022 OPPS quarterly update CR. These codes will be released to the public through the January OPPS quarterly update CRs and via the CMS HCPCS website (for Level II HCPCS codes).

For CY 2022, the Level II HCPCS codes effective January 1, 2022 are flagged with comment indicator ''NI'' in Addendum B to this final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2022. We are inviting public comments on the interim SI and APC assignments for these codes, if applicable, that will be finalized in the CY 2023 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Solicited Public Comments in the CY 2022 OPPS/ASC Proposed Rule

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid resorting to use of HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), to solicit public comments in the final rule, and to finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2022 OPPS update, we received the CPT codes that will be effective January 1, 2022 from the AMA in time to be included in the CY 2022 OPPS/ASC proposed rule. The new, revised, and deleted CPT codes can be found in Addendum B to the CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator ''NP'' in Addendum B of the CY 2022 OPPS/ASC proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator.

Further, we note that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and the long descriptors for the new and revised CY 2022 CPT codes in Addendum O to the CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website) so that the public can adequately comment on our proposed APCs and status indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled ''CY 2022 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code''. The final CPT code numbers would be included in this final rule with comment period. We also noted that not every code listed in Addendum O is subject to public comment. For the new and revised CPT codes, we requested public comments on only those codes that are assigned comment indicator ''NP''.

In summary, in the CY 2022 OPPS/ASC proposed rule, we solicited public comments on the proposed CY 2022 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2022. Because the CPT codes listed in Addendum B appear with short descriptors only, we listed them again in Addendum O to the CY 2022 OPPS/ASC proposed rule with long descriptors. In addition, we proposed to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in this final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to the CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

Commenters addressed several of the new CPT codes that were assigned to comment indicator ''NP'' in Addendum B of the 2022 OPPS/ASC Proposed Rule. We have responded to those public comments in sections III.D. ''OPPS APC-Specific Policies'' of this final rule with comment period.

Finally, in Table 9, which is a reprint of Table 7 from the CY 2022 OPPS/ASC proposed rule, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS.

BILLING CODE 4120–01–P

TABLE 9: COMMENT TIMEFRAME FOR NEW AND REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2021	HCPCS (CPT and Level II codes)	April 1, 2021	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
July 2021	HCPCS (CPT and Level II codes)	July 1, 2021	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
October 2021	HCPCS (CPT and Level II codes)	October 1, 2021	CY 2022 OPPS/ASC final rule with comment period	CY 2023 OPPS/ASC final rule with comment period
January 2022	CPT Codes	January 1, 2022	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2022	CY 2022 OPPS/ASC final rule with comment period	CY 2023 OPPS/ASC final rule with comment period

BILLING CODE 4120–01–C

B. OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in regulations at 42 CFR 419.31. We use Level I (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric codes) to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3. of this final rule with comment period.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2022, we proposed that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning)

the clinical integrity of the APC groups and the relative payment weights. We note that the HOP Panel recommendations for specific services for the CY 2022 OPPS update will be discussed in the relevant specific sections throughout this final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ''2 times rule''). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as for low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act (FDCA)). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In this section of the CY 2022 OPPS/ASC proposed rule, for CY 2022, we proposed to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

For the CY 2022 OPPS update, in the CY 2022 OPPS/ASC proposed rule, we identified the APCs with violations of the 2 times rule. Therefore, we proposed changes to the procedure codes assigned to these APCs in Addendum B to the CY 2022 OPPS/ASC proposed rule. We noted that Addendum B does not appear in the printed version of the **Federal Register** as part of the CY 2022 OPPS/ASC proposed rule. Rather, it is published and made available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity, we proposed to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2022 included in the CY 2022 OPPS/ASC proposed rule are related to changes in costs of services that were observed in the CY 2019 claims data available for CY 2022 ratesetting. Addendum B to the CY 2021 OPPS/ASC proposed rule identified with a comment indicator ''CH'' those procedure codes for which we proposed a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2021 OPPS Addendum B Update (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html*).

3. APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we proposed to make for CY 2022, we reviewed all of the APCs to determine which APCs would not meet the requirements of the 2 times rule. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

Based on the CY 2019 claims data available for the CY 2022 proposed rule, we found 23 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we proposed to make exceptions under the 2 times rule for CY 2022, and found that all of the 23 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2019 claims data available for the CY 2022 OPPS/ASC proposed rule. We did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have similar geometric mean costs and do not create a 2 times rule violation. Therefore, we only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with violations of the 2 times rule.

We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we may accept the HOP Panel's recommendation because those recommendations are based on explicit consideration (that is, a review of the latest OPPS claims data and group discussion of the issue) of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 8 of the CY 2022 OPPS/ASC proposed rule listed the 23 APCs for which we proposed to make an exception under the 2 times rule for CY 2021 based on the criteria cited above and claims data submitted between January 1, 2019 and December 31, 2019, and processed on or before June 30, 2020, and updated CCRs, if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of the CY 2022 OPPS/ASC proposed rule can be found on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

Based on the updated final rule CY 2019 claims data used for this final rule with comment period, we identified the same 23 APCs that appeared in Table 8 of the CY 2022 OPPS/ASC proposed rule.

Comment: We received two comments that agreed with the proposed exceptions identified in Table 8 of the CY 2021 OPPS proposed rule.

Response: We appreciate the commenters' support.

Comment: One commenter requested that CMS adjust the definition of a significant procedure code for cost significance purposes in evaluating the 2 times rule to only require 500 single claims rather than the current requirement of 1,000 single claims.

Response: As stated earlier, in determining whether a 2 times rule violation exists in an APC, we consider only those HCPCS codes that are significant based on the number of claims for the codes. For purposes of identifying significant HCPCS codes to examine for 2 times rule violations, we consider codes that have more than 1,000 single major claims or codes that have both greater than 99 single major

claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a HCPCS code for which there are fewer than 99 single claims and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost. We continue to believe that these definitions remain appropriate and are therefore making no changes in this final rule with comment period.

Comment: One commenter opposed the allowance of a 2 times rule exception for APC 5161 (Level 1 ENT Procedures) in Table 8 of the CY 2021 OPPS proposed rule, based on the current construct of codes included in the APC.

Response: We have reviewed the CY 2019 claims data available for CY 2022 OPPS ratesetting for APC 5161 and believe that this APC remains appropriate as currently structured because it optimizes clinical and resource cost homogeneity. In addition, we note that the 2 times rule violation is based on the cost range of approximately $155.55 for CPT code 31500 (Insert emergency airway) and $315.60 for CPT code 69100 (Biopsy of external ear) between the geometric mean costs for the lowest and highest cost significant codes in the APC. The difference between the geometric mean costs for CPT codes 31500 and 69100 violates the 2 times rule by a minimal amount and does not suggest there is a broader issue with the APC. However, we will continue to monitor the claims data for APC 5161 as they become available.

After considering the public comments we received on proposed APC assignments and our analysis of the CY 2019 costs from hospital claims and cost report data available for this final rule with comment period, we are finalizing our proposals, with some modifications. Specifically, we are finalizing our proposal to except the 23 proposed APCs from the 2 times rule for CY 2022.

Table 10 below lists the 23 APCs that we are excepting from the 2 times rule for CY 2022 based on the criteria described earlier and a review of claims data for dates of service between January 1, 2019, and December 31, 2019, that were processed on or before June 30, 2020. We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we generally accept the HOP Panel's recommendation because those recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates. The geometric mean costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule with comment period can be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

BILLING CODE 4120–01–P

TABLE 10: CY 2022 APC EXCEPTIONS TO THE 2 TIMES RULE

CY 2022 APC	CY 2022 APC Title
5051	Level 1 Skin Procedures
5055	Level 5 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5101	Level 1 Strapping and Cast Application
5112	Level 2 Musculoskeletal Procedures
5161	Level 1 ENT Procedures
5301	Level 1 Upper GI Procedures
5311	Level 1 Lower GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5593	Level 3 Nuclear Medicine and Related Services
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5673	Level 3 Pathology
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

BILLING CODE 4120–01–C

C. New Technology APCs

1. Background

In the CY 2002 OPPS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2021, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0–$10)) to the highest cost band assigned to APC 1908 (New Technology—Level 52 ($145,001–$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from $10 to $14,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level 7 ($501–$600)) is made at $550.50.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital market basket increase reduced by the productivity adjustment. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and are adequate to ensure access to services (80 FR 70374).

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Quite often, parties request that Medicare make higher payments under the New Technology APCs for new procedures in that transitional phase.

These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.

We note that, in a budget-neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2022, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to the CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

2. Establishing Payment Rates for Low-Volume New Technology Services

Services that are assigned to New Technology APCs are typically new services that do not have sufficient claims history to establish an accurate payment for the services. One of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new service so that it can be assigned to an appropriate clinical APC. Some services that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. We consider services with fewer than 100 claims annually to be low-volume services because there is a higher probability that the payment data for a service may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. In addition, services with fewer than 100 claims per year are not generally considered to be a significant contributor to the APC ratesetting calculations and, therefore, are not included in the assessment of the 2 times rule. As we explained in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58890), we were concerned that the methodology we use to estimate the cost of a service under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS service code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the service for these low-volume services.

In accordance with section 1833(t)(2)(B) of the Act, services classified within each APC must be comparable clinically and with respect to the use of resources. As described earlier, assigning a service to a New Technology APC allows us to gather claims data to price the service and assign it to the APC with services that use similar resources and are clinically comparable. However, where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access to new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we determined in the CY 2019 OPPS/ASC final rule with comment period that it was appropriate to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determined the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). We have utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to estimate an appropriate payment amount for low-volume new technology services in the past (82 FR 59281). Although we have used this adjustment authority on a case-by-case basis in the past, we stated in the CY 2019 OPPS/ASC final rule with comment period that we believed it was appropriate to adopt an adjustment for low-volume services assigned to New Technology APCs in order to mitigate the wide payment fluctuations that have occurred for new technology services with fewer than 100 claims and to provide more predictable payment for these services.

For purposes of this adjustment, we stated that we believed that it was appropriate to use up to 4 years of claims data in calculating the applicable payment rate for the prospective year, rather than using solely the most recent available year of claims data, when a service assigned to a New Technology APC has a low annual volume of claims, which, for purposes of this adjustment, we defined as fewer than 100 claims annually. We adopted a policy to consider services with fewer than 100 claims annually as low-volume services because there is a higher probability that the payment data for a service may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. We explained that we were concerned that the methodology we use to estimate the cost of a service under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS procedure code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the low-volume service. Using multiple years of claims data will potentially allow for more than 100 claims to be used to set the payment rate, which would, in turn, create a more statistically reliable payment rate.

In addition, to better approximate the cost of a low-volume service within a New Technology APC, we stated that we believed using the median or arithmetic mean rather than the geometric mean (which ''trims'' the costs of certain claims out) could be more appropriate in some circumstances, given the extremely low volume of claims. Low claim volumes increase the impact of ''outlier'' claims; that is, claims with either a very low or very high payment rate as compared to the average claim, which would have a substantial impact on any statistical methodology used to estimate the most appropriate payment rate for a service. We also explained that we believed having the flexibility to utilize an alternative statistical

methodology to calculate the payment rate in the case of low-volume new technology services would help to create a more stable payment rate. Therefore, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we would seek public comments on which statistical methodology should be used for each low-volume service assigned to a New Technology APC. In the preamble of each annual rulemaking, we stated that we would present the result of each statistical methodology and solicit public comment on which methodology should be used to establish the payment rate for a low-volume new technology service. In addition, we explained that we would use our assessment of the resources used to perform a service and guidance from the developer or manufacturer of the service, as well as other stakeholders, to determine the most appropriate payment rate. Once we identified the most appropriate payment rate for a service, we would assign the service to the New Technology APC with the cost band that includes its payment rate.

For CY 2022, we proposed to continue to utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using up to 4 years of claims data to select the appropriate payment rate for purposes of assigning services with fewer than 100 claims per year to a New Technology APC. However, we proposed to utilize our equitable adjustment authority through our proposed universal low volume APC policy described in section X.C. of the CY 2022 OPPS/ASC proposed rule. Our proposed universal low volume APC policy is similar to our current New Technology APC low volume policy with the difference between the two policies being that the universal low volume APC policy would apply to clinical APCs and brachytherapy APCs, in addition to procedures assigned to New Technology APCs, and would use the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to set the payment rate for the APC. For New Technology APCs with fewer than 100 single claims at the procedure level that can be used for ratesetting, we would apply our proposed methodology for determining a low volume APC's cost, choosing the ''greatest of'' the median, arithmetic mean, or geometric mean at the procedure level, to apply to the individual services assigned to New Technology APCs and provide the final New Technology APC assignment for each procedure. We proposed to end our separate New Technology APC low volume policy if we adopt the proposed universal low volume APC policy, as it also applies to New Technology APCs as well as clinical and brachytherapy APCs.

We did not receive any comments on our proposal to end our separate New Technology APC low volume policy if we adopt the proposed universal low volume APC policy and we have decided to implement our universal low volume APC policy as described in section X.C. of this final rule with comment period. Therefore, we are implementing our proposal without modification and applying our universal low volume APC policy to procedures assigned to New Technology APCs as well as clinical and brachytherapy APCs.

3. Procedures Assigned to New Technology APC Groups for CY 2022

As we described in the CY 2002 OPPS final rule (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC assignment, or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2022, we proposed to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if we have not obtained sufficient claims data. It also allows us to retain a service in a New Technology APC for more than 2 years if we have not obtained sufficient claims data upon which to base a reassignment decision (66 FR 59902).

a. Retinal Prosthesis Implant Procedure (APC 1908)

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis, specifically, a procedure involving the use of the Argus® II Retinal Prosthesis System. This first retinal prosthesis was approved by FDA in 2013 for adult patients diagnosed with severe to profound retinitis pigmentosa. For information on the utilization and payment history of the Argus® II procedure and the Argus® II device prior to CY 2020, please refer to the CY 2021 OPPS final rule (85 FR 85937 through 85938).

For CY 2020, we identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2015 through CY 2018. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $146,059, the arithmetic mean cost to be approximately $152,123, and the median cost to be approximately $151,267. All of the resulting estimates from using the three statistical methodologies fell within the same New Technology APC cost band ($145,001–$160,000), where the Argus® II procedure was assigned for CY 2019. Consistent with our policy stated in section III.C.2 of this final rule with comment period, we presented the result of each statistical methodology in the CY 2022 OPPS/ASC proposed rule, and we sought public comments on which method should be used to assign procedures described by CPT code 0100T to a New Technology APC. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fell within the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000. Accordingly, we assigned CPT code 0100T in APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a payment rate of $152,500.50 for CY 2020.

For CY 2021, the number of reported claims for the Argus® II procedure continued to be very low with a substantial fluctuation in cost from year to year. The high annual variability of the cost of the Argus® II procedure continued to make it difficult to establish a consistent and stable payment rate for the procedure. As previously mentioned, in accordance with section 1833(t)(2)(B) of the Act, we are required to establish that services classified within each APC are

comparable clinically and with respect to the use of resources. We identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2016 through CY 2019. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $148,148, the arithmetic mean cost to be approximately $153,682, and the median cost to be approximately $151,974. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fell within the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000, and accordingly, we assigned the Argus II procedure to New Technology APC 1908 for CY 2021.

For 2022, we proposed to utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to establish the universal low volume APC policy described in section X.C. of the CY 2022 OPPS/ASC proposed rule. Consistent with this proposed policy, we calculated the geometric mean, arithmetic mean, and median costs using multiple years of claims data to select the appropriate payment rate for purposes of assigning the Argus® II procedure (CPT code 0100T) to a New Technology APC. We proposed to use claims data from CY 2016 through CY 2019, which are the last 4 years of available OPPS claims data that we believe are appropriate for ratesetting, to determine the proposed payment rate for the Argus® II procedure for CY 2022. The claims data are the same 35 claims that were used to determine the payment rate for CPT code 0100T in CY 2021, and the estimates of the geometric mean ($148,148), the arithmetic mean ($153,682), and the median ($151,974) are the same as the estimates for CY 2021. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure are within the cost band for New Technology APC 1908, with the proposed payment rate being between $145,001 and $160,000. Accordingly, we proposed to continue to assign the Argus® II procedure to New Technology APC 1908 for CY 2022.

For our analysis for this final rule with comment period, we identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2016 through CY 2019, which were the same claims analyzed for the CY 2022 OPPS/ASC proposed rule. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $148,148, the arithmetic mean cost to be approximately $153,682, and the median cost to be approximately $151,974, which are the same results that we calculated for the proposed rule. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fall within the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000.

We received no public comments on our proposal. Therefore, we are finalizing our proposal without modification. We will maintain the assignment of the procedure described by CPT code 0100T in APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a payment rate of $152,500.50 for CY 2021. We note that the final payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). Please see Table 11 below for the final OPPS APC and status indicator for the Argus® II procedure (CPT code 0100T) for CY 2022.

TABLE 11: CY 2022 OPPS APC AND STATUS INDICATOR FOR THE ARGUS® II PROCEDURE (CPT CODE 0100T) ASSIGNED TO NEW TECHNOLOGY APC

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2022 OPPS Payment Rate
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intraocular retinal electrode array, with vitrectomy	T	1908	$152,500.50

b. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1561)

Effective January 1, 2021, CMS established HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) and assigned it to a New Technology APC based on the geometric mean cost of HCPCS code 67036. For CY 2021, HCPCS code C9770 was assigned to APC 1561 (New Technology—Level 24 ($3001–$3500)). This procedure may be used to describe the administration of CPT code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes). This procedure was previously discussed in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85939 through 85940).

CPT code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) is a gene therapy for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna®), was approved by FDA in December of 2017, and is indicated as an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.[20] This therapy is administered through a subretinal injection, which stakeholders describe as an extremely delicate and sensitive surgical procedure. The FDA package insert describes one of the steps for administering Luxturna as, ''after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana.''

Stakeholders, including the manufacturer of Luxturna®, recommended HCPCS code 67036 (Vitrectomy, mechanical, pars plana approach) for the administration of the gene therapy.[21] However, the manufacturer previously contended the administration was not accurately described by any existing codes as HCPCS code 67036 (Vitrectomy, mechanical, pars plana approach) does not account for the administration itself.

CMS recognized the need to accurately describe the unique administration procedure that is required to administer the therapy described by HCPCS code J3398. Therefore, in the CY 2021 OPPS/ASC proposed rule (85 FR 48832), we proposed to establish a new HCPCS code, C97X1 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process. We stated that we believed that this new HCPCS code accurately described the unique service associated with intraocular administration of HCPCS code J3398. We recognized that HCPCS code 67036 represents a clinically similar procedure and process that approximates similar resource utilization that is associated with C97X1. However, we also recognized that it is not prudent for the code that describes the administration of this unique gene therapy, C97X1, to be assigned to the same C–APC to which HCPCS code 67036 is assigned, as this would package the primary therapy, HCPCS code J3398, into the code that represents the process to administer the gene therapy.

Therefore, for CY 2021, we proposed to assign the services described by C97X1 to a New Technology APC with a cost band that contains the geometric mean cost for HCPCS code 67036. The placeholder code C97X1 was replaced by C9770 in this final rule with comment period. For CY 2021, we finalized our proposal to create C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent), and we assigned this code to APC 1561 (New Technology—Level 24 ($3,001–$3,500)) using the geometric mean cost of HCPCS code 67036. See Table 12 for the final descriptor and APC assignment of HCPCS code C9770 for CY 2021.

For CY 2022, we proposed to continue our policy from CY 2021 to assign the services described by HCPCS code C9770 to a New Technology APC with a cost band that contains the geometric mean cost for HCPCS code 67036. We proposed to continue to assign the services described by C9770 to a New Technology APC with a payment band based on the geometric mean cost for HCPCS code 67036 based on its geometric mean cost using CY 2019 claims data for CY 2022. Based on this data, the geometric mean cost of HCPCS code 67036 is $3,434.91. Therefore, we proposed to assign C9770 to the corresponding New Technology APC payment band, APC 1561 New Technology—Level 24 ($3,001–$3,500), with a payment rate of $3,250.50. Refer to Table 12 below for the proposed OPPS APC and status indicator for HCPCS code C9770 for CY 2022.

TABLE 12: CY 2021 FINAL AND CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9770 ASSIGNED TO NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	CY 2021 OPPS SI	CY 2021 OPPS APC	Proposed CY 2022 OPPS SI	Proposed CY 2022 OPPS APC
C9770	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1561	T	1561

[20] Luxturna. FDA Package Insert. *Available: https://www.fda.gov/media/109906/download.*

[21] LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS. *https://myspark generation.com/pdf/Reimbursement_Guide_for_Treatment_Centers_Interactive_010418_FINAL.pdf.*

We received no comment on this proposal. Therefore, we are finalizing our proposal as proposed to continue our policy from CY 2021 to assign the services described by HCPCS code C9770 to a New Technology APC with a cost band that contains the geometric mean cost for HCPCS code 67036. As we proposed to continue to assign the services described by C9770 to a New Technology APC with a payment band based on the geometric mean cost for HCPCS code 67036 based on its geometric mean cost using CY 2019 claims data for CY 2022, we are finalizing this proposal. Based on CY 2019 claims data, the geometric mean cost of HCPCS code 67036 is $3,435.25 Therefore, we will assign C9770 to the corresponding New Technology APC payment band, APC 1561 New Technology—Level 24 ($3,001–$3,500), with a payment rate of $3,250.50. Please see Table 13 below for the final and proposed OPPS APC and status indicator for HCPCS code C9770 for CY 2022.

TABLE 13: CY 2022 FINAL AND CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9770 ASSIGNED TO NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	Proposed CY 2022 OPPS SI	Proposed CY 2022 OPPS APC	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC
C9770	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1561	T	1561

c. Bronchoscopy With Transbronchial Ablation of Lesion(s) by Microwave Energy (APC 1562)

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3–D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (for example, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)). This microwave ablation procedure utilizes a flexible catheter to access the lung tumor via a working channel and may be used as an alternative procedure to a percutaneous microwave approach. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing services paid under the OPPS, we estimated the likely cost of the procedure would be between $8,001 and $8,500.

In claims data available for CY 2019 for the CY 2021 OPPS/ASC final rule with comment period, there were four claims reported for bronchoscopy with transbronchial ablation of lesions by microwave energy. Given the low volume of claims for the service, we proposed for CY 2021 to apply the policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs to calculate an appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC. We found the geometric mean cost for the service to be approximately $2,693, the arithmetic mean cost to be approximately $3,086, and the median cost to be approximately $3,708. The median was the statistical methodology that estimated the highest cost for the service and provided a reasonable estimate of the midpoint cost of the three claims that have been paid for this service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)). Therefore, we assigned HCPCS code C9751 to APC 1562 for CY 2021.

For CY 2022, the only available claims for HCPCS code C9751 are from CY 2019. Therefore, we proposed given the low number of claims for this procedure to utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs to calculate an appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC, consistent with our proposed universal low volume APC policy. Because we proposed to use the same claims as we did for CY 2021, we found the same values for the geometric mean cost, arithmetic mean cost, and the median cost for CY 2022. Once again, the median was the statistical methodology that estimated the highest cost for the service and provided a reasonable estimate of the midpoint cost of the three claims that have been paid for this service. The payment rate calculated using this methodology falls again within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)). Therefore, we proposed to continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3,501–$4,000)), with a proposed payment rate of $3,750.50 for CY 2022.

For our analysis for this final rule with comment period, we again used CY 2019 data, and we identified the same four claims reported for bronchoscopy with transbronchial ablation of lesions by microwave energy that were analyzed for the proposed rule and in CY 2021. Since the same claims were analyzed we received the same values for the geometric mean cost ($2,693), arithmetic mean cost ($3,086), and the median cost ($3,708) as we did for the proposed rule. As before, the median was the statistical methodology that estimated the highest cost for the service and provides a reasonable estimate of the midpoint cost of the three claims that have been paid for this service. The payment rate calculated using this methodology falls again within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)).

We did not receive any public comments regarding our proposal. We

are finalizing our proposal without modification to continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3,501–$4,000)), with a final payment rate of $3,750.50 for CY 2022. Details regarding HCPCS code C9751 are included in Table 14.

TABLE 14: CY 2022 OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9751 ASSIGNED TO NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2022 OPPS Payment Rate
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]	T	1562	$3,750.50

d. Fractional Flow Reserve Derived From Computed Tomography (FFRCT) (APC 1511)

Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow, is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow procedure is intended for clinically stable symptomatic patients with coronary artery disease, and, in many cases, may avoid the need for an invasive coronary angiogram procedure. HeartFlow uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether or not patients should undergo further invasive testing (that is, a coronary angiogram).

For many services paid under the OPPS, payment for analytics that are performed after the main diagnostic/image procedure are packaged into the payment for the primary service. However, in CY 2018, we determined that HeartFlow should receive a separate payment because the service is performed by a separate entity (that is, a HeartFlow technician who conducts computer analysis offsite) rather than the provider performing the CT scan. We assigned CPT code 0503T, which describes the analytics performed, to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50 based on pricing information provided by the developer of the procedure that indicated the price of the procedure was approximately $1,500. We did not have Medicare claims data in CY 2019 for CPT code 0503T, and we continued to assign the service to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50.

CY 2020 was the first year for which we had Medicare claims data to calculate the cost of HCPCS code 0503T. For the CY 2020 OPPS/ASC final rule with comment period, there were 957 claims with CPT code 0503T of which 101 of the claims were single frequency claims that were used to calculate the geometric mean of the procedure. We planned to use the geometric mean to report the cost of HeartFlow. However, the number of single claims for CPT code 0503T was below the low-volume payment policy threshold for the proposed rule, and this number of single claims was only two claims above the threshold for the New Technology APC low-volume policy for the final rule. Therefore, we decided to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using the CY 2018 claims data to determine an appropriate payment rate for HeartFlow using our New Technology APC low-volume payment policy. While the number of single frequency claims was just above our threshold to use the low-volume payment policy, we still had concerns about the normal cost distribution of the claims used to calculate the payment rate for HeartFlow, and we decided the low-volume payment policy would be the best approach to address those concerns.

Our analysis found that the geometric mean cost for CPT code 0503T was $768.26, the arithmetic mean cost for CPT code 0503T was $960.12, and the median cost for CPT code 0503T was $900.28. Of the three cost methods, the highest amount was for the arithmetic mean. The arithmetic mean fell within the cost band for New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)) with a payment rate of $950.50. The arithmetic mean helped to account for some of the higher costs of CPT code 0503T identified by the developer and other stakeholders that may not have been reflected by either the median or the geometric mean.

For CY 2021, we observed a significant increase in the number of claims billed with CPT code 0503T. Specifically, using CY 2019 data, we identified 3,188 claims billed with CPT code 0503T including 465 single frequency claims. These totals are well above the threshold of 100 claims for a procedure to be evaluated using the New Technology APC low-volume policy. Therefore, we used our standard methodology rather than the low-volume methodology we previously

used to determine the cost of CPT code 0503T. Our analysis found that the geometric mean for CPT code 0503T was $804.35, and the geometric mean cost for the service fell within the cost band for New Technology APC 1510 (New Technology—Level 10 ($801–$900)). However, providers and other stakeholders have noted that the FFRCT service costs $1,100 and that there are additional staff costs related to the submission of coronary CT image data for processing by HeartFlow.

We noted that HeartFlow is one of the first procedures utilizing artificial intelligence to be separately payable in the OPPS, and providers are still learning how to accurately report their charges to Medicare when billing for artificial intelligence services (85 FR 85943). This is especially the case for allocating the cost of staff resources between the HeartFlow procedure and the coronary CT imaging services. Therefore, we decided it would be appropriate to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to assign CPT code 0503T to the same New Technology APC in CY 2021 as in CY 2020 in order to provide payment stability and equitable payment for providers as they continue to become more familiar with the proper cost reporting for HeartFlow and other artificial intelligence services. Accordingly, we assigned CPT code 0503T to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)) with a payment rate of $950.50 for CY 2020, and we continued to assign CPT code 0503T to New Technology APC 1511 for CY 2021.

For CY 2022, we proposed to use claims data from CY 2019 to estimate the cost of the HeartFlow service. Because we are using the same claims data as in CY 2021, these data continue to reflect that providers were learning how to accurately report their charges to Medicare when billing for artificial intelligence services. Therefore, we proposed to continue to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to assign CPT code 0503T to the same New Technology APC in CY 2022 as in CY 2020 and CY 2021: New Technology APC 1511 (New Technology—Level 11 ($901–$1000)), with a payment rate of $950.50 for CY 2022, which is the same payment rate for the service as in CY 2020 and CY 2021.

Comment: The developer of HeartFlow and multiple other commenters stated that CPT code 0503T should not be assigned to New Technology APC 1510. Instead, they suggested that the HeartFlow procedure be assigned to APC 5593 (Level 3 Nuclear Medicine and Related Services) with a payment rate of around $1,270. The developer asserted that even though the payment for APC 5593 is substantially higher than the estimated cost of CPT code 0503T, the cost of the service fits reasonably well with the cost of other procedures assigned to APC 5593. The developer and other commenters also assert that the HeartFlow procedure has enough clinical similarity to other procedures currently assigned to the Nuclear Medicine and Related Services APCs. According to the developer and the other commenters, HeartFlow is comparable to other nuclear medicine procedures that are image analysis tests characterizing organ-specific function. The developer and the other commenters also note that cardiac CT procedures, which are used to identify coronary artery disease, are assigned to the nuclear medicine APC family. Finally, the developer cited two examples of procedures in the OPPS that are assigned to APCs where the procedure in question does not have clinical similarity to the other procedures in the APC.

Response: We disagree with the suggestion that CPT code 0503T should be assigned to APC 5593. As we stated in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85942), the Nuclear Medicine and Related Procedures APCs describe diagnostic and therapeutic procedures, many of them involving imaging, where radiopharmaceuticals and other nuclear materials are critical supplies for the performance of the procedure. In comparison, HeartFlow is a computer algorithm that does not directly take images nor is it used on its own to generate a diagnosis for a patient. Instead, HeartFlow analyzes diagnostic images obtained through other medical procedures and assists with the interpretation of those diagnostic images to determine if a patient has coronary artery disease. We appreciate that there may be a limited number of examples where a procedure may have only a little clinical similarity to other procedures in the same APC, but we attempt to make those situations an exception rather than our regular practice. There is little clinical similarity between the HeartFlow procedure and the procedures currently assigned to the Nuclear Medicine and Related Procedures APCs and we are therefore not assigning CPT code 0503T to APC 5593.

Comment: One commenter, the developer, suggested that, if we decided not to assign CPT code 0503T to a Nuclear Medicine and Related Services APC, that we assign the service to APC 5724 (Level 4—Level 4 Diagnostic Tests and Related Services) with a payment rate of $896.09. The commenter states Heartflow generates critical diagnostic information for the treating physician and an anatomical mapping of FFR values that assists the physician in determining whether an invasive procedure is needed for a patient. Because HeartFlow generates diagnostic information, the commenter believes it can be described as a diagnostic service or a service related to a diagnostic service and can be assigned to APC 5724. The commenter gives examples of software-based services that are already assigned to APC 5724 and notes that the geometric mean cost of CPT code 0503T places the service in the midrange of cost for separately paid services assigned to APC 5724.

Response: We appreciate the commenter's suggestion. However, one of the key reasons we assigned CPT code 0503T to a New Technology APC for CY 2021 and proposed assigning the service again to a New Technology APC for CY 2022, is that we are continuing to seek more cost data for the service before assigning it to a clinical APC. As mentioned earlier, we want to get a better understanding of the cost of HeartFlow as providers become more familiar with reporting and billing for artificial intelligence services. More broadly, we believe we need at least one more year of cost data before assigning HeartFlow to a clinical APC. Our concerns that the CY 2020 claims data and may not represent the outpatient hospital experience in CY 2022 make it challenging to refine or update our payment quality for HeartFlow given the need for additional claims data.

Comment: Several commenters asserted the proposed payment rate for CPT code 0503T is too low and does not reflect their individual hospital's cost to use HeartFlow. Commenters mentioned cost issues, including the $1,100 list price for each individual HeartFlow service and the staff resources involved to transmit data to the HeartFlow analysis facility and review the results of the analyses performed by HeartFlow. Commenters suggested a range of potential payments for a HeartFlow procedure from $1,151 up to $2,100, and they encouraged CMS to use our equitable adjustment authority at section 1833(t)(2)(E) of the Act to establish an OPPS payment rate that would more closely reflect the costs the commenters believe they are incurring to perform the HeartFlow procedure.

Response: For this final rule with comment period, we identified 3,188

claims billed with CPT code 0503T including 465 single frequency claims for CPT code 0503T using claims from CY 2019. Our analysis has found that the geometric mean for CPT code 0503T is $807.58, and the geometric mean cost is lower than the cost band for New Technology APC 1511 New Technology—Level 11 ($901–$1000) where CPT code 0503T is assigned. This result is similar to our results for the proposed rule and the CY 2021 OPPS/ASC final rule, which all used CY 2019 claims data. However, multiple commenters have noted that the FFRCT service costs $1,100 and that there are additional staff costs related to the submission of coronary CT image data for processing by HeartFlow. HeartFlow is one of the first procedures utilizing artificial intelligence to be separately payable in the OPPS, and providers are still learning how to accurately report their charges to Medicare when billing for artificial intelligence services. This is especially the case for allocating the cost of staff resources between the HeartFlow procedure and the coronary CT imaging services. Also, the COVID–19 PHE potentially has affected the quality of the claims and cost data from CY 2020, and we have decided not to use that data to determine the payment rate for CPT code 0503T. That means it is difficult to determine whether the additional costs for HeartFlow that commenters state that their practices are incurring are reflected in the cost data for the service.

Therefore, we believe it is appropriate to continue to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to assign CPT code 0503T to the same New Technology APC in CY 2022 as in CY 2020 and CY 2021 in order to provide payment stability and equitable payment for providers as they continue to become more familiar with the proper cost reporting for HeartFlow and other artificial intelligence services until we can review more recent reliable claims data. As mentioned earlier in this section, CPT code 0503T was assigned to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50 for CY 2020, and we will continue to assign CPT code 0503T to New Technology APC 1511 for CY 2022.

After reviewing all of the public comments, we are finalizing our proposal without modification to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to continue to assign CPT code 0503T to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) for CY 2022. Refer to Table 15 below for the final OPPS APC and status indicator for CPT code 0503T for CY 2022.

TABLE 15: CY 2022 OPPS APC AND STATUS INDICATOR FOR CPT CODE 0503T ASSIGNED TO NEW TECHNOLOGY APC

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2022 OPPS Payment Rate
0503T	Noninvasive estimated coronary fractional flow reserve (ffr) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated ffr model	S	1511	$950.50

e. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1522 and 1523)

Effective January 1, 2020, we assigned three CPT codes (78431, 78432, and 78433) that describe the services associated with cardiac PET/CT studies to New Technology APCs. Table 16 lists the code descriptors, status indicators, and APC assignments for these CPT codes. CPT code 78431 was assigned to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50. CPT codes 78432 and 78433 were assigned to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50. We did not receive any claims data for these services for CY 2021. Therefore, we continued to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50. Likewise, CPT codes 78432 and 78433 continued to be assigned to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50.

For CY 2022, we proposed to use CY 2019 claims data to determine the payment rates for CPT codes 78431, 78432, and 78433. Because these codes did not become active until CY 2020, there are no claims for these three services. Accordingly, we proposed to continue to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50. Likewise, we proposed that CPT codes 78432 and 78433 would continue to be assigned to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50.

Comment: Multiple commenters supported our proposal to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50, and to assign CPT codes 78432 and 78433 to APC 1523 (New Technology—Level 23

($2501–$3000)) with a payment rate of $2,750.50. Commenters noted that there were no available claims data for these services as we are using CY 2019 claims data for CY 2022 ratesetting, and these codes did not become active until January 2020.

Response: We appreciate the support of the commenters for our policy. After our review of the public comments, we have decided to implement our proposal without modification. Table 16 lists code descriptors, status indicators, and APC assignments for these CPT codes.

BILLING CODE 4120–01–P

TABLE 16: CY 2022 OPPS APC AND STATUS INDICATOR FOR CPT CODES 78431, 78432, AND 78433 ASSIGNED TO NEW TECHNOLOGY APCS

CPT Code	Long Descriptor	CY 2021 OPPS SI	CY 2021 OPPS APC	Final CY 2022 OPPS SI	Final OPPS CY 2022 APC
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1522	S	1522
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability);	S	1523	S	1523
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	S	1523	S	1523

BILLING CODE 4120–01–C

f. V-Wave Medical Interatrial Shunt Procedure (APC 1590)

A randomized, double-blinded, controlled IDE study is currently in progress for the V-Wave interatrial shunt. The V-Wave interatrial shunt is for patients with severe symptomatic heart failure and is designed to regulate left atrial pressure in the heart. All participants who passed initial screening for the study receive a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also receive the V-Wave interatrial shunt procedure while participants assigned to the control group only receive right heart catheterization. The developer of V-Wave was concerned that the current coding of these services by Medicare would reveal to the study participants whether they have received the interatrial shunt because an additional procedure code, CPT code 93799 (Unlisted cardiovascular service or procedure), would be included on the claims for participants receiving the interatrial shunt. Therefore, for CY 2020, we created a temporary HCPCS code to describe the V-wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography

(ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study) to describe the service, and we assigned the service to New Technology APC 1589 (New Technology—Level 38 ($10,001–$15,000)).

We stated in the CY 2021 OPPS/ASC final rule with comment period that we believe that similar resources and device costs are involved with the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure (85 FR 85946). Therefore, the difference in the payment for HCPCS codes C9758 and C9760 is based on how often the interatrial shunt is implanted when each code is billed. An interatrial shunt is implanted one-half of the time HCPCS code C9758 is billed. Accordingly, for CY 2021, we reassigned HCPCS code C9758 to New Technology APC 1590, which reflects the cost of having surgery every time and receiving the interatrial shunt one-half of the time when the procedure is performed.

For CY 2022, we are using the same claims data that we did for CY 2021. Because there are no claims reporting HCPCS code C9758, we proposed to continue to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of $17,500.50 for CY 2022.

Comment: Multiple commenters including the manufacturer supported our proposal to continue to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of $17,500.50 for CY 2022.

Response: We appreciate the support of the commenters for our proposal. After reviewing the public comments, we are finalizing our proposal without modification. Details about the HCPCS code and its APC assignment are shown in Table 17. The final CY 2022 payment rate for C9758 can be found in Addendum B to this final rule with comment period.

TABLE 17: CY 2022 OPPS APC AND STATUS INDICATOR FOR BLINDED INTRATRIAL SHUNT PROCEDURE ASSIGNED TO A NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	Final 2022 OPPS SI	Final 2022 OPPS APC
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1590

g. Corvia Medical Interatrial Shunt Procedure (APC 1592)

Corvia Medical is currently conducting its pivotal trial for their interatrial shunt procedure. The trial started in Quarter 1 of CY 2017 and is scheduled to continue through CY 2021.[22] On July 1, 2020, we established HCPCS code C9760 (Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study) to facilitate the implantation of the Corvia Medical interatrial shunt.

As we stated in the CY 2021 OPPS final rule with comment period, we believe that similar resources and device costs are involved with the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure (85 FR 85947). Therefore, the difference in the payment for HCPCS codes C9760 and C9758 is based on how often the interatrial shunt is implanted when each code is billed. The Corvia Medical interatrial shunt is implanted every time HCPCS code C9760 is billed. Therefore, for CY 2021, we assigned HCPCS code C9760 to New Technology APC 1592 (New Technology—Level 41 ($25,001–$30,000)) with a payment rate of $27,500.50. We also modified the code descriptor for HCPCS code C9760 to remove the phrase ''or placebo control,'' from the descriptor. For CY 2022, we proposed to use the same claims data as in CY 2021 to establish payment rates for services. Therefore, there are no claims for HCPCS code C9760, and we proposed to continue to assign HCPCS code C9760 to New Technology APC 1592.

Comment: Multiple commenters, including the manufacturer, supported our proposal to continue to assign HCPCS code C9760 to New Technology APC 1592.

Response: We appreciate the support of the commenters of our proposal.

Comment: One commenter, the manufacturer, requested that CPT code 0613T (Percutaneous transcatheter implantation of interatrial septal shunt device, including right and left heart catheterization, intracardiac echocardiography, and imaging guidance by the proceduralist, when performed) be assigned to comprehensive APC 5194 (Level 4

[22] *https://clinicaltrials.gov/ct2/show/NCT03088033?term=NCT03088033&rank=1.*

Endovascular Procedures) for CY 2022 and assigned a status indicator of ''J1''. CPT code 0613T is the CPT code that will be used to report the Corvia Medical interatrial shunt procedure once the Corvia Medical interatrial shunt device associated with the procedure receives approval from the FDA, which the manufacturer believes will occur in CY 2022. Currently, CPT code 0613T is a non-payable service code and is assigned a status indicator of ''E1''.

Response: We will assign CPT code 0613T to a payable status indicator and assign the service to a clinically-appropriate APC when the Corvia Medical interatrial shunt device associated with the procedure has received approval from the FDA. OPPS payment policies are updated quarterly through a sub-regulatory process. If the Corvia Medical interatrial shunt device receives FDA approval, we will work to ensure a timely transition for the overall procedure to be reported with CPT code 0613T and end reporting of the service with HCPCS code C9760. We will also work to assign CPT code 0613T to an APC that reflects clinical and resource similarity to CPT code 0613T.

Details about the HCPCS code and its APC assignment are shown in Table 18. The final CY 2022 payment rate for C9760 can be found in Addendum B to this final rule with comment period.

TABLE 18: CY 2022 OPPS APC AND STATUS INDICATOR FOR NON-RANDOMIZED, NON-BLINDED INTRATRIAL SHUNT PROCEDURE ASSIGNED TO A NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	Final 2022 OPPS SI	Final 2022 OPPS APC
C9760	Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (eg, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	T	1592

h. Supervised Visits for Esketamine Self-Administration (APCs 1508 and 1511)

On March 5, 2019, FDA approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant, for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression (TRD)). Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for abuse and misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

A treatment session of esketamine consists of instructed nasal self-administration by the patient, followed by a period of post-administration observation of the patient under direct supervision of a health care professional. Esketamine is a noncompetitive N-methyl D-aspartate (NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. This is the first FDA approval of esketamine for any use. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients would require either two (2) devices (for a 56 mg dose) or three (3) devices (for an 84 mg dose) per treatment.

Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for abuse and misuse of the product, Spravato is only available through a restricted distribution system under a REMS; patients must be monitored by a health care provider for at least 2 hours after receiving their Spravato dose; the prescriber and patient must both sign a Patient Enrollment Form; and the product will only be administered in a certified medical office where the health care provider can monitor the patient. Please refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine self-administration (84 FR 63102 through 63105).

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020. HCPCS code G2082 is for an outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine through nasal self-administration and includes 2 hours post-administration observation. HCPCS code G2082 was assigned to New Technology APC 1508 (New Technology—Level 8 ($601—$700)) with a payment rate of $650.50. HCPCS code G2083 describes a similar

service to HCPCS code G2082, but involves the administration of more than 56 mg of esketamine. HCPCS code G2083 was assigned to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50.

For CY 2022, we are using CY 2019 claims data to determine the payment rates for HCPCS codes G2082 and G2083. Since these codes did not become active until CY 2020, there are no claims for these two services. Therefore, for CY 2022, we proposed to continue to assign HCPCS code G2082 to New Technology APC 1508 (New Technology—Level 8 ($601–$700)) and to assign HCPCS code G2083 to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)).

Comment: One commenter, the manufacturer, while understanding the rationale for our proposal to use CY 2019 claims data for CY 2022 ratesetting, asked us to take into consideration CY 2020 claims data to finalize payment rates for HCPCS codes G2082 and G2083. The commenter noted that HCPCS codes G2082 and G2083 were not payable in CY 2019, and therefore there is no cost information in the CY 2019 claims data for these two procedures. The commenter also believes that CY 2020 data may show that the cost of G2082 and G2083 is substantially higher than the current New Technology APC assignments for the two services.

Response: We reviewed the available CY 2020 OPPS claims data in response to the request by the commenter for HCPCS codes G2082 and G2083, but we decided that there were not enough data available to determine whether to change the APC assignments for HCPCS codes G2082 and G2083. We would like to review another year of claims data for HCPCS codes G2082 and G2083 to assess the reliability of the cost information for CY 2020 and CY 2021 before using claims data to base our APC assignments for these services. Therefore, we will continue to use the same APC assignments for HCPCS codes G2082 and G2083 for CY 2022 as for CY 2021.

After reviewing the public comments for this proposal, we have decided to implement our proposal without modification to assign HCPCS code G2082 to New Technology APC 1508 and to assign HCPCS code G2083 to New Technology APC 1511. Details about the HCPCS codes and their APC assignments are shown in Table 19. The final CY 2022 payment rate for esketamine self-administration can be found in Addendum B to this final rule with comment period.

TABLE 19: CY 2021 OPPS APC AND STATUS INDICATOR FOR ESKETAMINE SELF-ADMINISTRATION HCPCS CODES ASSIGNED TO NEW TECHNOLOGY APCS

HCPCS Code	Long Descriptor	CY 2021 OPPS SI	CY 2021 OPPS APC	Final CY 2022 OPPS SI	Final CY 2021 OPPS APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1508	S	1508
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	S	1511	S	1511

i. DARI Motion Procedure (APC 1505)

CPT code 0693T (Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report) will be effective January 1, 2022. The technology consists of eight cameras that surround a patient. The cameras send live video to a computer workstation that analyzes the video to create a 3D reconstruction of the patient without the need for special clothing, markers or devices attached to the patient's clothing or skin. The technology is intended to guide health care providers on pre and post-operative surgical intervention and on the best course of physical therapy and rehabilitation for patients.

As displayed in Addendum B to the CY 2022 OPPS/ASC proposed rule, we

proposed to assign CPT code 0693T to APC 5721 (Level 1 Diagnostics and Related Services) with a proposed payment rate of $143.21. We note that CPT code 0693T was listed as placeholder code 0X60T in OPPS Addendum B of the CY 2021 OPPS/ASC proposed rule.

Comment: One commenter, the manufacturer of the DARI Motion procedure, requested that CMS assign CPT code 0693T to APC 5723 (Level 3 Diagnostics and Related Services) with a payment rate of $498.53. The commenter believed that the payment rate for APC 5721 is inadequate and will create a barrier to patient access.

Response: We appreciate the concerns of the commenter and, for the reasons set forth below, agree that the proposed payment rate for CPT code 0693T may be too low and the procedure should be reassigned to a different APC.

The AMA releases Category III codes in January, for implementation beginning the following July, and in July, for implementation beginning the following January. DARI Motion received a Category III code scheduled for implementation January 1, 2022. Some Category III CPT codes describe services that we have determined are not compatible with an existing clinical APC, yet are appropriately provided in the hospital outpatient setting. In these cases, we may assign the Category III CPT code to what we estimate is an appropriately priced New Technology APC (71 FR 68015). In addition, it should be noted that, with all new codes, CMS's policy has been to assign the service to an APC based on input from a variety of sources, including but not limited to review of the clinical similarity of the service to existing procedures, input from CMS medical advisors, information from interested specialty societies, review of all other information available to us, including information provided to us by the public, whether through meetings with stakeholders or additional information that is mailed or otherwise communicated to us. Based on information from the manufacturer, resources involved for the procedure described by CPT code 0693T appear to be higher than the payment rate for APC 5721 (Level 1 Diagnostics and Related Services). CPT code 0693T is new for CY 2022 and, therefore, we had no claims data available for OPPS ratesetting. Further, based on input from our medical advisors and our understanding of the service, we believe that it is more appropriate to assign the DARI Motion procedure to APC 1505 (New Technology—Level 5 ($301–$400)), for CY 2022. We believe that assigning CPT code 0693T to New Technology APC 1505 will allow CMS to collect claims data before assigning CPT code 0693T to a clinical APC.

Comment: A commenter argued the assignment of CPT code 0693T to APC 5721 would create a 2 times rule violation within the APC based on geometric mean costs. The commenter calculated the 2-times threshold by multiplying the lowest cost significant procedure by 2 and arrived at a 2-times threshold. According to the commenter, the 2-times threshold they calculated for APC 5721 is a lower payment rate than the technology described by CPT code 0693T. The commenter asserted that assigning CPT code 0693T to APC 5721 is a violation of the 2 times rule.

Response: We thank the commenter for their feedback. To clarify, we determine APC 2 times rule violations by considering only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). CPT code 0693T is new for CY 2022 and, therefore, we had no claims data available for purposes of determining whether a 2 times rule violation occurs based on the code.

In summary, after consideration of the public comments, we are finalizing our proposal with modification, and assigning CPT code 0693T to New Technology APC 1505 (New Technology—Level 5 ($301–$400)), for CY 2022. The final APC assignment and status indicator for CPT code 0693T are found in Table 20. We refer readers to Addendum B of this final rule with comment period or the final payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

As we do for all codes, we will reevaluate the APC assignments for CPT code 0693T once we have claims data. We remind hospitals that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on the latest claims data.

TABLE 20: FINAL CY 2022 STATUS INDICATOR AND APC ASSIGNMENT FOR THE DARI MOTION PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2022 OPPS SI	Proposed CY 2022 OPPS APC	Proposed CY 2022 OPPS Payment Rate	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2022 OPPS Payment Rate
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	S	5721	$143.21	S	1505	Refer to OPPS Addendum B

j. Histotripsy Service (APC 1575)

Histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy targeted cancerous liver tumors. The AMA's CPT Editorial Panel established a new code to describe the service associated with histotripsy, specifically, Category III CPT code, 0686T (Histotripsy (that is, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance), effective July 1, 2021.

As displayed in Addendum B of the CY 2022 OPPS/ASC proposed rule with comment period, for CY 2022, we proposed to assign the new code to APC 5311 (Level 1 Lower GI Procedures) with a payment rate of $814.44 effective January 1, 2022.

Comment: One commenter, the manufacturer of histotripsy, stated that histotripsy is a new technology that delivers short pulses of ultrasound energy, resulting in acoustic cavitation that mechanically destroys the targeted cancerous liver tumors while avoiding damage to intervening or surrounding healthy tissues. The commenter stated that the proposed assignment of CPT code 0686T to APC 5311 (Level 1 Lower GI Procedures) was not clinically or resource cohesive to histotripsy. The commenter reported a list of HCPCS codes currently assigned to APC 5311 and argued that the codes are not clinically or resource similar to histotripsy. The commenter referenced histotripsy's IDE clinical study (G200253–NCT04573881) and provided a description of the histotripsy procedure and a breakdown of the associated resource components. The commenter also provided a cost estimate of each resource, such as the device cost, the associated imaging cost, and total room time. The commenter stated that the total cost for the procedure is $22,782.51 and requested assignment to a New Technology APC 1577 for the histotripsy service.

Response: We appreciate the commenter's input on this new technology. As stated in the CY 2002 OPPS final rule, CMS staff will obtain information on cost from other appropriate sources before making a final determination on the cost of the procedure or service to hospital outpatient facilities (66 FR 59900). We note that for Category A IDE studies, Medicare may not furnish payment for costs associated with the histotripsy device since Category A devices are statutorily excluded from Medicare coverage. Based on our evaluation, for CY 2022, we estimated the cost of histotripsy, after removing the device cost, is within the cost band between $10,001 and $15,000. Accordingly, we believe reassigning CPT code 0686T to APC 1575 (New Technology—Level 38 ($10,001–$15,000)), with a payment rate of $12,500.50, more appropriately reflects the costs for which Medicare may provide payment. We note that we retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC.

In summary, after consideration of the public comments, we are finalizing our proposal with modifications. Specifically, we are assigning CPT code 0686T to APC 1575 for CY 2022. The final CY 2022 OPPS payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addenda B and D1 are available via the internet on the CMS website.

k. Liver Multiscan Service (APC 1511)

Liver MultiScan is a Software as a medical Service (SaaS) that is intended to aid the diagnosis and management of chronic liver disease, the most prevalent of which is Non-Alcoholic Fatty Liver Disease (NAFLD). It provides standardized, quantitative imaging biomarkers for the characterization and assessment of inflammation, hepatocyte ballooning, and fibrosis, as well as steatosis, and iron accumulation. The SaaS receives MR images acquired from patients' providers and analyzes the images using their proprietary Artificial Intelligence (AI) algorithms. The SaaS then send the providers a quantitative metric report of the patient's liver fibrosis and inflammation. The AMA CPT Editorial Panel established two new codes, specifically, Category III CPT codes 0648T and 0649T for LiverMultiScan effective July 1, 2021, and CMS assigned the Category III CPT code 0648T to APC 5523 (Level 3 Imaging without Contrast) with a status indicator of ''S'' effective July 1, 2021. We note that CPT code 0649T is packaged per our packaging policy for add-on code procedures. For the complete code descriptors for both codes, refer to Table 21.

For CY 2022, we proposed to assign CPT code 0648T to APC 5523 (Level 3 Imaging without Contrast) with a payment rate of $236.14 effective January 1, 2022, and assign the add-on code, CPT code 0649T, to OPPS status indicator ''N'' (packaged) to indicate that payment for the add-on service is included in the primary service.

TABLE 21: PROPOSED OPPS SI FOR CPT CODES 0648T AND 0649T

CPT Code	Long Description	Proposed OPPS SI
0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	S
0649T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	N

Comment: Several commenters stated that LiverMultiScan is a new technology that represents a breakthrough for the diagnosis and monitoring of chronic parenchymal liver disease that will reduce the number of invasive procedures. The commenters stated that LiverMultiScan is an MRI measure of hepatic steatosis with performance equivalent to liver biopsy and superior to liver fat measures using ultrasound. Some commenters cited that biopsy is the gold standard for diagnosis, but it is not commonly used because of cost, patient discomfort, risk of complications, and possible sampling error. Another commenter stated that LiverMultiScan has excellent diagnostic accuracy for at-risk Nonalcoholic steotohepatitis (NASH), detects changes in response to investigational treatments within a very short timeframe, and predicts clinical outcomes in patients with liver disease as well as liver biopsy. The commenters believe LiverMultiScan improves the management of NAFLD by helping patients connect with their liver health, which encourages these patients to their recommended course of treatment. The commenters stated the assignment of CPT code 0648T to APC 5523 (Level 3 Imaging without Contrast) does not adequately cover the cost of delivering this service and discourages adoption of advanced liver care. The commenters stated that their hospital outpatient cost for the service is between $1,300 to $1,500 (versus approximately $7,000 for a liver biopsy), and they requested assignment of LiverMultiScan to a New Technology APC. One commenter referenced CMS's decision on Heartflow, which was initially packaged and then later recognized as a distinct service. The commenter requested CMS recognize LiverMultiScan as a distinct service.

Response: We appreciate the commenters' feedback on this new technology. We note that before we assign a new service to a New Technology APC, we first perform our own cost analysis and cost estimate. As we stated in the CY 2002 OPPS final rule (66 FR 59900), we do not limit our determination of the cost of the procedure to information suggested by the commenters (or information submitted by the applicant for New Technology applications). To appropriately assign a service to a New Technology APC, our staff will obtain information on cost from other appropriate sources, including acquiring input from our medical advisors on the appropriateness of the service in the hospital outpatient setting, before making a final determination on the cost of the procedure or service. Based on the information provided, we recognize that LiverMultiScan is a new technology that will aid in the management of beneficiaries with NAFLD, which may avoid liver biopsies. We note that liver biopsy remains the current gold standard for diagnosing NASH, determining grade disease severity, and accurately staging fibrosis. Based on our evaluation of the service, we agree with the commenter's suggested reference to Heartflow. That is, we believe that LiverMultiScan and Heartflow share similar characteristics based on the nature of how the service is provided in the hospital outpatient setting. Both LiverMultiScan and Heartflow require the acquisition of radiological images as well as analysis of the images using proprietary AI algorithms to assist clinicians in appropriately diagnosing a patient's medical condition. In addition, our analysis of the estimated cost associated for this service is between $901 and $1,000. Therefore, after further evaluation of the service and the resources required to perform the LiverMultiScan analysis, we believe it is appropriate to assign this service to a New Technology APC, specifically, APC 1511 (New Technology—Level 11 ($901–$1000)), which is the same APC assignment for Heartflow. Accordingly, we are assigning CPT code 0648T to New Technology APC 1511). We note that we retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. For CPT code 0649T, an add-on code, we believe that our assignment of the status indicator of ''N'' is appropriate under 42 CFR 419.2(b). We note that CMS does not create the Category III CPT codes or their descriptors, but we follow an established set of payment policies consistent with our OPPS packaging policy. As stated in section III.A. ''OPPS Treatment of New and Revised HCPCS Codes'' of this final rule with comment period, CPT codes are established and maintained by the American Medical Association (AMA), and changes to CPT codes should be referred to the AMA.

In summary, after consideration of the public comment, we are finalizing our proposal with modification, to assign CPT code 0648T to New Technology APC 1511 ((New Technology—Level 11 ($901–$1000), for CY 2022. Also, we are finalizing our proposal, without

modification, for CPT code 0649T and assigning the code to OPPS status indicator ''N'' for CY 2022. The final APC assignment and status indicators for CPT codes 0648T and 0649T can be found in OPPS Addendum B. We refer readers to Addendum B of the final rule for the final payment rates for all codes reportable under the OPPS. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and Addendum D1 are available via the internet on the CMS website.

l. Minimally Invasive Glaucoma Surgery (MIGS) (APCs 5491 and 5492)

Prior to CY 2022, extracapsular cataract removal with insertion of intraocular lens was reported using CPT codes describing cataract removal alongside a CPT code for device insertion. Specifically, the procedure was described using CPT codes 66982 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (for example, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation) or 66984 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation) and 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion). For CY 2022, the AMA's CPT Editorial Panel created two new Category I CPT codes describing extracapsular cataract removal with insertion of intraocular lens prosthesis, specifically, CPT codes 66989 and 6691, deleted a Category III CPT code, specifically, CPT code 0191T, describing insertion of anterior segment aqueous drainage device, and created a new Category III CPT code, specifically, CPT code 0671T, describing interior segment aqueous drainage device without concomitant cataract removal. We proposed the following APC assignment:

- CPT code 66989 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (*e.g.,* irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (*e.g.,* iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more) to APC 5492 (Level 2 Intraocular Procedures) with a proposed status indicator (SI) of ''J1'' and proposed payment rate of $4,018.82. We note this code was listed as placeholder code 669X1 in the OPPS Addendum B of the CY 2022 OPPS/ASC proposed rule.
- CPT code 66991 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification); with insertion of intraocular (for example, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more) to APC 5492. We note this code was listed as placeholder code 669X2 in the OPPS Addendum B of the CY 2022 OPPS/ASC proposed rule.
- CPT code 0671T (Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more) to APC 5491 (Level 1 Intraocular Procedures) with a proposed SI of ''J1'' and a proposed payment rate of $2,131.25. We note this code was listed as placeholder code 0X12T in the OPPS Addendum B of the CY 2022 OPPS/ASC proposed rule.

At the August 23, 2021 HOP Panel Meeting, a presenter requested that we reassign CPT codes 66989 and 66991 to APC 5493 (Level 3 Intraocular Procedures) with a proposed payment rate of $7,529.00, and reassign 0671T to APC 5492, citing concerns over a decrease in payment for MIGS between how it is currently coded and how it will be coded beginning January 1, 2022. Based on the discussion during the meeting, the HOP Panel recommended that CMS reassign CPT codes 66989 and 66991 to APC 5493 and reassign 0671T to APC 5492.

Comment: Most commenters opposed the proposed APC assignment for these services and recommended that CMS implement the APC assignments recommended by the HOP Panel. They stated that the proposed APC assignments do not accurately account for the costs associated with MIGS and would result in an overall decrease in payment for MIGS from the current payment rates and that this decrease would negatively impact access to this service. Commenters stated placement in APC 5493 and APC 5492 would better account for the resources associated with performing CPT codes 66989 and 66991, and CPT code 0671T, respectively. Commenters also suggested that CMS could consider assignment of these services to a New Technology APC or create an incremental intraocular APC between APC 5492 and 5493.

Response: We do not believe that the costs associated with performing MIGS are accurately reflected by APC 5493. We note that while APC 5491 (Level 1 Intraocular Procedures) and APC 5492 have 40 or greater separately payable services assigned to them, only one service is assigned to the APCs 5493, 5494, and 5495 (Level 3–5 Intraocular Procedures, respectively). In instances where a single procedure is assigned to an APC, the geometric mean cost and the resulting payment rate is largely based on the geometric mean of the individual service assigned to the APC. However, we note that while only one service is assigned to APC 5493, there are certain complexity adjustments that move certain services assigned to the APC 5492 to APC 5493 when billed concurrently. These changes are also reflected in the claims data we use to develop geometric mean costs and the resulting payment rates. We note that the proposed payment rate for APC 5493 is almost double the payment rate for APC 5492. We also believe that the change in coding for MIGS is significant in that it changes longstanding billing for the service from reporting two separate CPT codes to reporting a single bundled code. Without claims data, and given the magnitude of the coding change, we do not believe we have the necessary information on the costs associated with CPT codes 66989 and 66991 to assign them to a clinical APC at this time. We agree with commenters that reassignment to a New Technology APC will maintain payment accuracy for these services while we collect cost data to support reassignment to the relevant clinical APC. We believe that APC 1526 (New Technology—Level 26 ($4001–$4500)), with a payment rate of $4,250.50, most accurately accounts for the resources associated with furnishing MIGS.

We regard to CPT code 0671T, we note that this code describes insertion of

intraocular lens without concurrent cataract removal and would not be billed alongside CPT codes 66989 or 66991. Based on our review of the clinical characteristics of the procedure and input from our medical advisors, we continue to believe that this service is more similar to the other services in APC 5491.

In summary, after consideration of the public comments, we are finalizing the reassignment of CPT codes 66989 and 66991 to APC 1526 and assignment of CPT code 0671T to APC 5491. The final CY 2022 OPPS payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

m. Scalp Cooling (APC 1520)

For July 1, 2021, the CPT Editorial Panel created CPT code 0662T to describe initial measurement and calibration of a scalp cooling device for use during chemotherapy administration to prevent hair loss. For CY 2022, we proposed to assign CPT code 0662T (Scalp cooling, mechanical; initial measurement and calibration of cap) to APC 5732 (Level 2 Minor Procedures) with a proposed payment rate of $34.72.

At the August 23, 2021 HOP Panel Meeting, a presenter requested that we reassign CPT code 0662T to one of the following APCs:

- APC 5054 (Level 4 Skin Procedures) with a proposed payment rate of $1,759.21,
- APC 5055 (Level 5 Skin Procedures) with a proposed payment rate of $3,613.14,
- APC 1519 (New Technology—Level 19 ($1,701–$1,800)) with a proposed payment rate of $1,750.50, or
- APC 1520 (New Technology—Level 20 ($1,801–$1,900)) with a proposed payment rate of $1,850.50

Based on the information presented, the HOP Panel recommended that CMS assign CPT code 0662T to a New Technology APC.

Comment: Commenters encouraged CMS to accept the HOP Panel's recommendation and assign CPT code 0662T to APC 1519 or 1520 or reassign CPT code 0662T to either APC 5054 or 5055. Commenters stated that the cost of the scalp cooling cap itself was around $600 and that the rest of the costs associated with performing the measurement and calibration were around $2,500–$3,000.

Response: Based on the information presented at the HOP Panel meeting, as well as input from our clinical advisors, and analysis of the information provided by the commenters, we believe that the procedure described by CPT code 0662T should be assigned to a New Technology APC. We note that according to Medicare's National Coverage Determination (NCD) policy, specifically, NCD 110.6 (Scalp Hypothermia During Chemotherapy to Prevent Hair Loss), the scalp cooling cap itself is classified as an incident to supply to a physician service, and would not be paid under the OPPS; however, stakeholders have indicated that there are substantial resource costs associated with calibration and fitting of the cap. Based on the estimate of costs provided by the commenter, without taking into account the costs of the cap, the overall cost associated with CPT code 0662T is between $1,900–$2,400, supporting reassignment to New Technology APC 1520. CPT guidance states that CPT code 0662T should be billed once per chemotherapy session, which we interpret to mean once per course of chemotherapy. Therefore, if a course of chemotherapy involves 6 or 18 sessions, HOPDs should report CPT 0662T only once for that 6 or 18 therapy sessions. We note that we review, on an annual basis, the APC assignments for all items and services paid under the OPPS.

In summary, after consideration of the public comments, we are finalizing our proposal with modification. Specifically, we are finalizing assignment of CPT code 0662T to APC New Technology 1520. The final CY 2022 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

D. OPPS APC-Specific Policies

1. AccuCinch Ventricular Restoration Procedure

For the July 2021 update, the AMA's CPT Editorial Panel established CPT code 0643T (Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach) to describe the AccuCinch device implantation procedure. For CY 2022, we proposed to assign the code to OPPS status indicator ''E1'' (Items, codes, and services not covered by any Medicare outpatient benefit category; statutorily excluded; not reasonable and necessary) to indicate that the service is not covered by Medicare.

Comment: A commenter requested the reassignment in the status indicator to OPPS status indicator ''C'' (inpatient-only) since this is the more appropriate assignment for the ventricular restoration therapy based on the complex patient population enrolled in the US clinical trial. The commenter explained that the investigational device, the AccuCinch® Ventricular Restoration System, is currently under evaluation in the CORCINCH–HF pivotal trial (NCT04331769).

Response: Based on our review of the clinical study, input from our medical advisors, as well review of Medicare's coverage policy for this clinical trial, we agree with the commenter. Review of the clinical study indicates that the CORCINCH–HF study (*https://clinicaltrials.gov/ct2/show/NCT04331769*) is a prospective, randomized, control multicenter clinical study that evaluates the safety and efficacy of the AccuCinch Ventricular Restoration System in patients with heart failure and reduced ejection fraction (HFrEF). Based on the interventional structural heart (SH) technique involved in the procedure, use of an experimental device, and close monitoring of the patient that is required during the intra- and post-op period consistent with the resources available in the hospital inpatient setting, we believe the AccuCinch procedure should be designated as an inpatient-only procedure. We note that the CORCINCH–HF pivotal trial (NCT04331769) was approved by Medicare and meet's CMS' standards for coverage as an Investigation Device Exemption (IDE) study effective November 11, 2020.

In summary, after consideration of the public comment, we are modifying our proposal and revising the status indicator for CPT code 0643T from ''E1'' to ''C'' (inpatient-only) for CY 2022. We refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

2. Administration of Lacrimal Ophthalmic Insert Into Lacrimal Canaliculus (APC 5694)

HCPCS code J1096 (Dexamethasone, lacrimal ophthalmic insert, 0.1 mg) is a drug indicated ''for the treatment of ocular inflammation and pain following

ophthalmic surgery.'' [23] Stakeholders assert that this drug is administered through CPT code 0356T (Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each). Stakeholders also state the drug is inserted in a natural opening in the eyelid (called the punctum) and that the drug is designed to deliver a tapered dose of dexamethasone to the ocular surface for up to 30 days. HCPCS code J1096 is currently on pass-through status and assigned to APC 9308 (Dexametha opth insert 0.1 mg) with status indicator ''G''. Please see section V.A.5. of this final rule with comment period for further information regarding the pass-through status of J1096. CPT code 0356T is currently assigned to status indicator ''Q1'', indicating conditionally packaged payment under the OPPS. Packaged payment applies if a code assigned status indicator ''Q1'' is billed on the same claim as a HCPCS code assigned status indicator ''S'', ''T'', or ''V''. Accordingly, based on the OPPS assigned status indicator, CPT code 0356T is assigned to payment indicator ''N1'' in the ASC setting, meaning a packaged service/item. We refer readers to Addendum D1 of this final rule with comment period for a list of OPPS status indicators and their definitions, available via the internet on the CMS website. We also refer readers to Addendum AA for ASC payment indicator assignments and to Addendum DD1 for payment indicator definitions, available via the internet on the CMS website. For CY 2021, CPT code 0356T is assigned to APC 5692 (Level 2 Drug Administration). Effective January 1, 2022, CPT code 0356T will be deleted. CPT code 68841, represented by placeholder code 68XXX in the proposed rule, will become effective on January 1, 2022.

Due to the similarity between CPT code 0356T and CPT code 68841, we proposed to assign CPT code 68841 to the same APC, status indicator, and payment indicator assignments as CPT code 0356T.

Additionally, we note that the manufacturer of the product that is usually administered through 0356T and placeholder code 68XXX, brought the issue of payment of this code to the Advisory Panel on Hospital Outpatient Payment (also known as HOP Panel) in 2021 for CY 2022 rulemaking and requested a new APC placement. The HOP Panel did not make a recommendation to reassign placeholder code 68XXX to a different APC, OPPS status indicator, or ASC payment indicator as suggested by the presenters.

Comment: Commenters asserted that the proposed placeholder code 68XXX is used to describe the administration of Dextenza and the drug insertion procedure is typically performed after the completion of an ophthalmic procedure, such as a cataract, glaucoma, or retina procedure. Commenters state this procedure is typically done in the ASC setting 80 percent of the time, and is performed in the HOPD setting 20 percent of the time.

Several commenters had concerns with continuing the same APC placement of APC 5692 for CPT code 68XXX for CY 2022. Commenters generally advocated for increased payment for this CPT code in the HOPD and ASC settings. Some commenters did not make a specific suggestion as to what the final APC assignment should be, rather they argued the proposed payment was inadequate. However, some commenters made specific recommendations to change the APC assignment to APC 5503 (Level 3 Extraocular, Repair and Plastic Eye Procedures). Commenters felt this would be a more appropriate and fair APC placement due to its resource similarity to procedures in this APC. Commenters frequently cited CPT 66030 (Injection, anterior chamber of eye (separate procedure); medication) and CPT 0X78T (Injection, posterior chamber of eye; medication), which were proposed to be assigned to APC 5491 (Level 1 Intraocular Procedures), as similar procedures to which 68XXX should be compared. However, commenters did recognize that 68XXX represents an extraocular procedure; therefore, they felt APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures) would be an appropriate alternative APC assignment.

A minority of commenters discussed the proposed status indicator assignment and payment indicator assignment for 68XXX. Some said a ''Q1'' status indicator was inappropriate, but did not provide an alternative suggestion. One commenter provided an alternate crosswalk for 68XXX and stated that, in their view, 68XXX was clinically similar to CPT Code 68761 (Closure of the lacrimal punctum; by plug, each), which is assigned to APC 5501 (Level 1 Extraocular, Repair and Plastic Eye Procedures), and is assigned to status indicator ''T''.

Additionally, a commenter mentioned using available 2020 claims data for 0356T, instead of the zero claims data available using 2019 claims as proposed, which would suggest a higher APC placement.

Several stakeholders commented that the clinical importance of providing HCPCS code J1096 to patients is that it reduces ocular pain, inflammation, and reduces the burden of topical eyedrop application. Additionally, providers stated that they usually perform the procedure to administer Dextenza after the conclusion of ophthalmic surgeries. Commenters believe the procedure is a distinct surgical procedure that requires additional operating room time and resources. Commenters were concerned that the lack of increased or separate payment may reduce access to Dextenza, particularly in the ASC setting.

Response: We thank commenters for their feedback. We note that placeholder code 68XXX will be replaced by CPT code 68841, and we will refer to this code from here on. Based on input from stakeholders, we believe an APC reassignment is appropriate for CY 2022. After careful consideration of the statements from commenters, we analyzed available claims data and similar procedures that approximate the clinical resources associated with CPT code 68841. We agree with a commenter that CPT code 68761 (Closure of the lacrimal punctum; by plug, each) may more appropriately approximate the resources associated with CPT code 68841. We also believe that CPT code 68801 (Dilation of lacrimal punctum, with or without irrigation) represents a clinically similar procedure and would also be an appropriate procedure with which to compare CPT code 68841. Additionally, based on our review of comments, we do not find it appropriate to use the three single frequency claims that are associated with the CY 2020 claims data for CPT code 0356T as a basis for CPT code 68841, as they seem anomalous compared to the 1,543 total frequency claims available in the CY 2020 claims data dataset. Additionally, we do not find it appropriate to use CY 2019 claims data for 0356T as there are zero single frequency claims, 53 total frequency claims, and a zero-dollar geometric mean. Rather, we believe estimating the clinical resources needed for CPT code 68841 through comparison to clinically similar codes is more appropriate for CY 2022.

Based on the CY 2019 claims data available for CY 2022 OPPS ratesetting, the geometric mean cost associated with CPT code 68761 is $211.17 and the geometric mean cost associated with CPT code 68801 is $300.27. Based on these geometric mean costs, we believe assignment of CPT code 68841 to APC 5694 (Level 4 Drug Administration) is

[23] Dextenza FDA Package Insert: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208742s001lbl.pdf.*

appropriate. Additionally, we continue to believe that assignment of CPT code 68841 to an OPPS status indicator ''Q1'' and an associated ASC payment indicator of ''N1'', is appropriate. Commenters have stated that CPT code 68841 is performed during ophthalmic surgeries, such as cataract surgeries. A status indicator ''Q1'', conditionally packaged procedure, describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor ''N1'') under the ASC payment system. Although stakeholders state this is an independent surgical procedure and should not be packaged into the primary ophthalmic procedure in which the drug and drug administration are associated, based on stakeholder comment regarding clinical patterns as to how the drug is used, we do not agree. We find it appropriate to conditionally package CPT code 68841 based on its clinical use patterns as described by commenters. This is consistent with 42 CFR 419.2(b). The conditional packaging of this code supports our overarching goal to make payments for all services paid under the OPPS and ASC payment system more consistent with those of a prospective payment system and less like those of a per-service fee schedule. We believe that packaging encourages efficiency and is an essential component of a prospective payment system, and that packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service is a fundamental part of the OPPS. We therefore believe packaging of CPT code 68841 is appropriate.

After consideration of the public comments, we are finalizing our proposal to assign CPT code 68841 to APC 5694 (Level 4 Drug Administration) with OPPS status indicator ''Q1'' for CY 2022. In addition, based on the OPPS assignments, we are finalizing an ASC payment indicator of ''N1'' for CPT code 68841 for CY 2022. Please see Table 22 for the code descriptor, APC assignment, status indicator assignment, and payment indicator assignment for CPT code 68841 for CY 2022.

TABLE 22: PROPOSED AND FINAL APC, SI, AND PI FOR CPT CODE 68841 FOR CY 2022

CPT Code	Long Descriptor	Proposed OPPS APC	Proposed OPPS SI	Proposed ASC PI	Final OPPS APC	Final OPPS SI	Final ASC PI
68841*	Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each	5692	Q1	N1	5694	Q1	N1

*CPT code 68841 was listed as placeholder code 68XXX in OPPS Addendum B of the CY 2022 OPPS/ASC proposed rule with comment period.

3. Allergy Testing (APC 5724)

For CY 2022, we proposed to continue to assign CPT code 95004 (Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests) and CPT code 95044 to APC 5724 (Level 4 Diagnostic Tests and Related Services) with a proposed payment rate of $943.96.

Comment: One commenter expressed concerns with the overall reimbursement for allergy testing, stating that reimbursement has increased dramatically over time for what the commenter asserted was a relatively routine procedure. The commenter recommended that CMS review the payment rates for these services to ensure that they are being accurately reimbursed.

Response: We thank the commenter for their insight and will consider it for future rulemaking.

In summary, after consideration of the public comment, we are finalizing our proposal without modification. Specifically, we are finalizing assignment of CPT codes 95004 and 95044 to APC 5724. The final CY 2022 OPPS payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

4. Blood Not Otherwise Classified (NOC) (APC 9537)

Providers and stakeholders in the blood products field have reported that product development for new blood products has accelerated. There may be several additional new blood products entering the market by the end of by CY 2022, compared to only one or two new products entering the market over the previous 15 to 20 years. To encourage providers to use these new products, providers and stakeholders requested that we establish a new HCPCS code to allow for payment for unclassified blood products prior to these products receiving their own HCPCS code. Under the OPPS, unclassified procedures are generally assigned to the lowest APC payment level of an APC family. However, since blood products are each assigned to their own unique APC, the concept of a lowest APC payment level does not apply in this context.

Starting January 1, 2020, we established a new HCPCS code, P9099 (Blood component or product not otherwise classified) which allows providers to report unclassified blood products. We assigned HCPCS code P9099 to status indicator ''E2'' (Not payable by Medicare when submitted on an outpatient claim) for CY 2020. We took this action because HCPCS code P9099 potentially could be reported for multiple products with different costs during the same period of time. Therefore, we could not identify an individual blood product HCPCS code that would have a similar cost to HCPCS code P9099, and were not able to crosswalk a payment rate from an

established blood product HCPCS code to HCPCS code P9099. Some stakeholders expressed concerns that assigning HCPCS code P9099 to a non-payable status in the OPPS meant that hospitals would receive no payment when they used unclassified blood products. Also, claim lines billed with P9099 are rejected by Medicare, which prevents providers from tracking the utilization of unclassified blood products.

Because of the challenges of determining an appropriate payment rate for unclassified blood products, we stated in the CY 2021 OPPS/ASC proposed rule that we were considering packaging the cost of unclassified blood products into their affiliated primary medical procedure. Although we typically do not package blood products under the OPPS, for unclassified blood products, we stated that we do not believe it is possible to accurately determine an appropriate rate that would apply for all of the products (potentially several, with varying costs) that may be reported using HCPCS code P9099. Packaging the cost of unclassified blood products into the payment for the primary medical service by assigning HCPCS code P9099 a status indicator of ''N'' would allow providers to report the cost of unclassified blood products to Medicare. Over time, the costs of unspecified blood products would be reflected in the payment rate for the primary medical service if the blood product remains unclassified. However, we stated that we expect that most blood products would seek and be granted more specific coding such that the unclassified HCPCS code P9099 would no longer be applicable. We also explained that we believe that packaging the costs of unclassified blood products would be an improvement over the current non-payable status for HCPCS code P9099 as it would allow for tracking of the costs and utilization of unclassified blood products. We had concerns about this approach because providers would not receive separate payment for the blood products reported with HCPCS code P9099, and providers would have had to wait at least two years for the primary service billed with HCPCS code P9099 to potentially reflect some of the cost of the unclassified product. After considering the other payment options for HCPCS code P9099 and comments from providers and stakeholders, we decided against packaging HCPCS code P9099 for CY 2021.

The CMS HOP Panel and multiple stakeholders suggested another payment alternative to have unclassified blood products paid separately by using a weighted average of the payment rates of all separately payable blood products in the OPPS. The average payment rate would be weighted by the number of units billed for each service in the OPPS. Stakeholders believed a weighted average would be consistent with OPPS policy to provide separate payment for all blood products and would encourage the use of HCPCS code P9099 to track the utilization of unclassified blood products until the new products could receive individual HCPCS codes. Other stakeholders suggested that unclassified blood products be paid either at charges reduced to cost or at reasonable cost to appropriately compensate providers billing unclassified blood products.

We decided against paying for HCPCS code P9099 through either a weighted average payment, charges reduced to cost, or reasonable cost for CY 2021. We had concerns that these payment methods could provide incentives to discourage manufacturers of new blood products from seeking individual HCPCS codes for their products. A weighted average payment would encourage manufacturers of relatively inexpensive unclassified blood products not to seek a HCPCS code for their products because the payment using HCPCS code P9099 for the products would be substantially higher than payment the products would receive once an individual code is established for the blood products. In addition, the level of payment from a weighted average payment may reduce the urgency of manufacturers to seek an individual HCPCS code even for higher-cost products, which would delay our ability to track payment for individual blood products.

After considering our options, we decided for CY 2021 to pay for HCPCS code P9099 by making the blood not otherwise classified code separately payable, assigning it a status indicator of ''R'', and paying the code at a rate equal to the lowest paid separately payable blood product in the OPPS, which is P9043 (Infusion, plasma protein fraction (human), 5 percent, 50 ml) with a payment rate of $7.79 per unit. This policy aligns with our overall OPPS policy to pay NOC codes at the lowest available APC rate for a service category, while providing a payment for unclassified blood products when a service is reported on the claim. Our policy also provides incentives for manufacturers to seek individual HCPCS codes for new blood products, which helps us to track the utilization of these new blood products and establish a payment rate for these new products that better reflects their cost. For CY 2022, we proposed to continue our policy that was established in CY 2021 without modification.

Comment: The HOP Panel and multiple commenters have requested that unclassified blood products assigned to HCPCS code P9099 be paid based on reasonable cost and that HCPCS code P9099 be assigned a status indicator of ''F'' (paid at reasonable cost). Unclassified blood products paid on the basis of reasonable cost would receive payment based on individual invoices submitted by the provider that detail the actual cost of the unclassified blood products for the provider. The commenters believe our current policy severely underpays for most unclassified blood products, which limits the ability of providers to use these new products, and discourages innovation in the blood products field. Commenters assert that the universe of blood products is very heterogeneous with each product having its own APC and payment rate, and our policy that assigns unclassified clinical services HCPCS codes to the lowest-paying APC in a clinical series is not appropriate for the payment of blood products.

Commenters also believe the administrative burdens of submitting claims to receive payment through reasonable cost would encourage blood product manufacturers to classify their unclassified products. Relatedly, two other commenters urged us to reduce administrative burden for providers if we decide to implement reasonable cost payment for HCPCS code P9099.

Response: We have concerns about paying unclassified blood products using reasonable cost and assigning HCPCS code P9099 a status indicator of ''F''. Although reasonable cost would likely provide a more granular reflection of the cost of unclassified blood products to providers, there would be no incentive for providers to manage their costs when using unclassified blood products, and no incentives for the manufacturers to seek individual HCPCS codes for the unclassified blood products. We agree with the commenters that the administrative burdens of seeking payment through reasonable cost methodology may provide some incentive to classify currently unclassified blood products. However, we believe that providers will prefer to receive full cost reimbursement for an unclassified blood product rather than risk receiving a prospective payment that could be less than full cost of the blood product if the blood product is classified and assigned a HCPCS code. Finally, we do not support reasonable cost payment for HCPCS code P9099 because the OPPS is a prospective payment system, and we

want to limit rather than expand the types of services within the OPPS that do not receive prospective payment.

After reviewing the public comments we received, we have decided to implement our proposal without modification to keep HCPCS code P9099 separately payable with a status indicator of ''R'', and pay the code at a rate equal to the lowest paid separately payable blood product in the OPPS, which is P9043 (Infusion, plasma protein fraction (human), 5 percent, 50 ml) with a payment rate of $7.79 per unit. Therefore, we are finalizing our proposal to continue to assign HCPCS code P9099 to APC 9537 (Blood component/product noc) for CY 2022. We appreciate that establishing a fair and equitable payment methodology for HCPCS code P9099 continues to be a challenge, and we plan to explore other possible ideas for the payment of HCPCS code P9099 in future rulemaking.

5. Bone Substitute Material Injection (APC 5113)

For January 1, 2022, the AMA's CPT Editorial Panel established new CPT code 0707T (Injection(s), bone substitute material (for example, calcium phosphate) into subchondral bone defect (that is, bone marrow lesion, bone bruise, stress injury, microtrabecular fracture), including imaging guidance and arthroscopic assistance for joint visualization). We note that CPT code 0707T was listed as placeholder code 0X79T in OPPS Addendum B of the CY 2022 OPPS/ASC proposed rule. For CY 2022, we proposed to assign CPT code 0707T to APC 5111 (Level 1 Musculoskeletal Procedures) with a proposed payment rate of $211.47.

Comment: Commenters did not agree with our proposed APC assignment. Instead, commenters stated that CPT code 0707T should be assigned to APC 5114 (Level 4 Musculoskeletal Procedure) with a proposed payment rate of $6,428.51 based on its clinical and resource homogeneity to the procedures and services in the APC. Commenters stated that 0707T is most clinically similar to Zimmer Biomet's AccuFill BSM procedure, which is the service described by CPT code 29855 (Arthroscopically aided treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed (includes arthroscopy)), and assigned to APC 5114. Commenters stated that the injection of a bone substitute material into a subchondral bone defect is mainly accounted for by two products, Zimmer Biomet's AccuFill BSM and Anika, which range in price from $2,600–$2,800.

Response: We do not agree that CPT code 0707T is comparable to CPT code 29855; however, based on our review of the clinical characteristics of the procedure and input from our medical advisors, we believe CPT code 0707T is more similar to the procedures assigned to APC 5113 (Level 3 Musculoskeletal Procedures) with a proposed payment rate of $2,906.75, and this payment rate better accounts for the cost of the procedure as well as the bone substitute material.

In summary, after consideration of the public comments, we are assigning CPT code 0707T to APC 5113 for CY 2022 based on its resource and clinical similarity to the procedures in APC 5113. The final CY 2022 OPPS payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

As we do every year, we will reevaluate the APC assignment for CPT code 0707T for the next rulemaking cycle. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

6. Calculus Aspiration With Lithotripsy Procedure (APC 5376)

For CY 2022, we proposed to assign HCPCS code C9761 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy (ureteral catheterization is included) and vacuum aspiration of the kidney, collecting system and urethra if applicable) to APC 5375 (Level 5 Urology and Related Services) with a proposed payment of $4,527.23. HCPCS code C9761 describes the procedure that uses a sterile, single-use aspiration-irrigation catheter that is designed to assist in the removal of stone fragments during standard ureteroscopy. Based on our analysis of the latest CY 2020 claims data for this CY 2022 OPPS/ASC final rule with comment period, our data reveals two single claims for HCPCS code C9761 with a geometric mean cost of $9,342.

Comment: Several commenters expressed concerns that a significant difference between cost and payment prevented hospitals from providing this procedure to their patients. The commenters urged CMS to change the APC assignment of HCPCS code C9761 to APC 5376 (Level 6 Urology and Related Services). The commenters asked that CMS assign HCPCS code C9761 to APC 5376 for two reasons: (1) The current and proposed reimbursement rates for services in APC 5375 are inadequate to pay hospitals appropriately for the costs of furnishing the Steerable Ureteroscopic Renal Evacuation (SURE) procedure; and (2) the clinical characteristics and resources associated with HCPCS code C9761 are similar to codes in APC 5376 than services in APC 5375.

Response: We thank the commenters for their feedback. Based on information from the manufacturer, resources involved for the procedure described by HCPCS code C9761 appear to be higher than for those procedures assigned to APC 5375. At this time, only two CY 2020 claims are available to assist in identifying costs associated with the procedure. The geometric mean cost of $9,342 for the two claims indicate that the cost of HCPCS code C9761 is substantially higher than the proposed payment rate of $4,527.23. However, two claims is not a significant data set; and we have concerns that the costs reported from the two claims for the procedure described by HCPCS code C9761 may not accurately reflect the geometric mean costs of the procedure. We also note that, in the manufacturer's 2020 New Technology APC application, they indicated that an appropriate payment for the procedure described by HCPCS code C9761 would be approximately $5,627.39 and that assignment to New Technology APC 1566 (New Technology—Level 29 ($5,501–$6,000)) would be appropriate. Based on the claims data along with the reported costs associated with the procedure presented to us by the manufacturer, we believe that it is appropriate to assign the procedure described by HCPCS code C9761 to APC 5376 (Level 6 Urology and Related Services), for CY 2022. As we do every year we will reevaluate the APC assignment for CPT code 9761 in the next rulemaking cycle. We remind hospitals that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on the latest claims data available to us.

In summary, after consideration of the public comments we received, we are modifying our proposal for the APC assignment of HCPCS code C9761. Instead of assigning this code to APC 5375 (Level 5 Urology and Related Services), for CY 2022, we are reassigning HCPCS code C9761 to APC 5376 (Level 6 Urology and Related Services). Table 23 below lists the final CY 2022 status indicator and APC assignments for the calculus aspiration

with lithotripsy procedure. We refer readers to Addendum B to this final rule with comment period for the final payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 23: FINAL SI AND APC ASSIGNMENT FOR HCPCS CODE C9761

HCPCS Code	Long Descriptor	Final OPPS SI	Final OPPS APC
C9761	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy (ureteral catheterization is included) and vacuum aspiration of the kidney, collecting system and urethra if applicable	J1	5376

7. Cardiac Computed Tomography (CT) (APC 5571)

For CY 2022, we proposed to continue to assign the following cardiac CT exam codes to APC 5571 (Level 1 Imaging with Contrast) with a proposed payment rate of $183.30:

- 75572 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3d image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed));
- 75573 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3d image postprocessing, assessment of lv cardiac function, rv structure and function and evaluation of venous structures, if performed)); and
- 75574 (Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3d image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)).

Comment: Many commenters opposed the assignment of CPT codes 75572, 75573, and 75574 to APC 5571. They stated that the proposed CY 2022 OPPS payment rate for APC 5571 is inadequate to cover the total cost of providing the service.

Commenters stated that they also believe that the resource costs required to perform cardiac CT scans are similar to the tests that are assigned to APC 5573 rather than APC 5571. They noted that the low payment for the test limits patient access, and requested that CMS take action to increase reimbursement to levels in line with the actual testing costs. The commenters requested an APC reassignment for all three codes. Specifically, the commenters suggested reassigning CPT codes 75572 and 75573 to APC 5572 (Level 2 Imaging with Contrast) and CPT code 75574 to APC 5573 (Level 3 Imaging with Contrast). Most of the commenters reported that cardiac CT scans are more resource intensive than other CT and x-ray scans in APC 5571 and expressed concerns that APC-misallocation would suppress utilization for these services.

Response: As we stated in the CY 2021 OPPS final rule with comment period (85 FR 85956), payments under the OPPS are based on our analysis of the latest available claims and cost report data submitted to Medicare. We have many years of claims data for CPT codes 75572, 75573, and 75574. Based on the geometric mean costs for these codes, we do not believe that CPT codes 75572, 75573, and 75574 utilize similar resources as the exams assigned to APC 5572 or APC 5573. We refer readers to the CY 2021 OPPS final rule with comment period for a more detailed discussion of the pricing methodology for CPT codes 75572, 75573, and 75574 (85 FR 85956 through 85959).

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, to assign the cardiac CT exam codes, specifically, CPT codes 75572, 75573, and 75574 to APC 5571. The final CY 2022 OPPS payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

8. Cardiac Magnetic Resonance (CMR) Imaging (APC 5523, 5524, 5572, and 5573)

For CY 2022, we proposed to continue to assign the following cardiac magnetic resonance imaging (MRI) CPT codes to APC 5523, 5524, 5572, and 5573, respectively:

- CPT code 75557 (Cardiac magnetic resonance imaging for morphology and function without contrast material) to APC 5523 (Level 3 Imaging without Contrast) with a proposed payment of $236.14;
- CPT code 75559 (Cardiac magnetic resonance imaging for morphology and function without contrast material; with stress imaging) to APC 5524 (Level 3 Imaging without Contrast) with a proposed payment of $495.76;
- CPT code 75561 (Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences) to APC 5572 (Level 2 Imaging with Contrast) with a proposed payment of $377.80; and
- CPT code 75563 (Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences; with stress imaging) to APC 5573 (Level 3 Imaging with Contrast) with a proposed payment of $733.76.

Comment: A few commenters expressed concern with the lack of payment stability for cardiac MRI services, specifically, those described by CPT codes 75557, 75559, 75561, and 75563. They indicated that the payments for these codes have decreased in the last several years, and prior to CY 2017, the codes were placed in appropriate APCs. Of significant concern are the payment rates for CPT codes 75561 and 75563, which, according to the commenters, are grouped with services that are not

clinically similar. The commenters stated that CPT code 75561 is unlike CT of the abdomen or pelvis or MRI of the neck and spine in APC 5572, and instead, the code should be placed in APC 5573 with comparable services. The commenters further added that CPT code 75563 is labor-intensive and should be assigned to APC 5593 (Level 3 Nuclear Medicine and Related Services).

Response: As stated in the CY 2021 OPPS final rule with comment period, payments under the OPPS are based on our analysis of the latest available claims and cost report data submitted to Medicare. We have many years of claims data for CPT codes 75561 and 75563. Based on the geometric mean costs for these codes, we do not believe that CPT codes 75561 and 75563 utilize similar resources as the exams assigned to APC 5573 or APC 5593. We refer readers to the CY 2021 OPPS final rule with comment period for a more detailed discussion of the pricing methodology for CPT codes 75561 and 75563 (85 FR 85959 through 85960).

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, to assign the cardiac MRI codes, specifically, CPT codes 75561 and 75563 to APCs 5572 and 5573. The final CY 2022 OPPS payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

9. Chimeric Antigen Receptor Therapy (CAR–T) (APCs 5694, 9035, 9194, 9391, 9413, and 9422)

Chimeric Antigen Receptor T-Cell (CAR T-cell) therapy is a cell-based gene therapy in which T-cells are collected and genetically engineered to express a chimeric antigen receptor that will bind to a certain protein on a patient's cancerous cells. The CAR T-cells are then administered to the patient to attack certain cancerous cells and the individual is observed for potential serious side effects that would require medical intervention. We refer readers to previous discussions in the OPPS/ASC final rules with comment period for background regarding the specific CAR T-cell products, in both the CY 2020 OPPS/ASC final rule with comment period (84 FR 61231 through 61234) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58904 through 58908). In addition, for discussion about CY 2022 OPPS payment policies for separately paid drugs with pass-through status expiring or continuing in CY 2022, please see sections V.A.4. and V.A.5. of this final rule with comment period. The AMA created four Category III CPT codes that are related to CAR T-cell therapy, effective January 1, 2019. As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58904 through 58908), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61231 through 61234), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 85949 through 85951) we finalized our proposal to assign procedures described by CPT codes 0537T, 0538T, and 0539T to status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) to indicate that the services are not paid under the OPPS. The procedures described by CPT codes 0537T, 0538T, and 0539T describe the various steps required to collect and prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step used to manufacture a drug or biological. We also finalized that the procedures described by CPT code 0540T would be assigned status indicator ''S'' (Procedure or Service, Not Discounted when Multiple) and APC 5694 (Level 4 Drug Administration) for CY 2019, CY 2020, and CY 2021 and made no proposal to change the assignment for CY 2022. Additionally, the National Uniform Billing Committee (NUBC) established CAR T-cell-related revenue codes and a value code to be reportable on Hospital Outpatient Department (HOPD) claims effective for claims received on or after April 1, 2019. We made no specific proposal related to the CAR T-cell preparation codes, as described by CPT codes 0537T, 0538T, 0539T. As listed in Addendum B of the CY 2022 OPPS/ASC proposed rule, we proposed to continue to assign procedures described by these CPT codes, 0537T, 0538T, and 0539T, to status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) to indicate that the services are not paid under the OPPS. We proposed to continue to assign CPT code 0540T to status indicator ''S'' (Procedure or Service, Not Discounted when Multiple) and APC 5694 (Level IV Drug Administration).

Comment: Two commenters opposed our proposal to continue to assign status indicator ''B'' to CPT codes 0537T, 0538T, and 0539T for CY 2022. One commenter did not have a specific recommendation, but rather suggested CMS take into consideration the complex process and separately recognize the efforts associated with leukapheresis, cell handling, and processing. This commenter additionally mentioned the administrative burden associated with CAR T-cell therapy administration, among other resources that are specific to the process in which CAR–T is processed, manufactured, and then administered.

The other commenter discussed a wide variety of topics related to CAR T-cell therapy and stated that a change in status indicator would be appropriate, with a preference for assigning CPT codes 0537T, 0538T, and 0539T to status indicator ''Q1''. This commenter believed that the procedures these CPT codes describe did not represent the steps required to manufacture the CAR T-cell product, as CMS has stated. Generally, this commenter advocated for a change in status indicator as they believed this change is necessary to allow services furnished to the patient to be eligible for payment and for hospitals to be paid appropriately for the services they provide during each step of the CAR T-cell process. This commenter pointed out that a number of patients may receive the preparation procedures, but then fail to receive the final CAR–T product. Accordingly, this commenter asked CMS to release new cost centers and to revise the instructions in MLN Matters Article SE19009 in order to no longer allow hospitals to put outpatient cell collection and process charges occurring more than three days prior to an inpatient stay on inpatient claims or to report cell collection and cell processing charges as part of the product charge.

Response: We thank the commenters for their feedback. CMS does not believe that separate or packaged payment under the OPPS is necessary for the procedures described by CPT codes 0537T, 0538T, and 0539T for CY 2022. The procedures described by CPT codes 0537T, 0538T, and 0539T describe the various steps required to collect and prepare the genetically modified T-cells; and Medicare does not generally pay separately for each step used to manufacture a drug or biological product. Additionally, we note that CAR T-cell therapy is a unique therapy approved as a biologic, with unique preparation procedures, that cannot be directly compared to other therapies or existing CPT codes. We note that the current HCPCS coding for the currently approved CAR T-cell therapies include leukapheresis and dose preparation procedures, as these services are included in the manufacturing of these

biologicals. Therefore, payment for these services is incorporated into the drug codes. Please see Table 24 for HCPCS coding for CAR T-cell therapies.

TABLE 24: CAR T-CELL THERAPIES FINAL SI AND APC ASSIGNMENTS FOR HCPCS CODES Q2041, Q2042, Q2053, Q2054, AND Q2055 FOR CY 2022

HCPCS Code	Long Descriptor	Final CY 2022 APC
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	9035
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	9194
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	9391
Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	9413
Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	9422

We note that although there is no payment associated with CPT codes 0537T, 0538T, and 0539T for reasons stated previously, these codes can still be reported to CMS for tracking purposes. We thank commenters for their feedback related to our guidance contained in MLN Matters Article SE19009. We are not revising this document at this time as we believe these instructions are consistent with our longstanding policies, but we appreciate the feedback from stakeholders. We believe that the comments in reference to payment for services in settings not payable under the OPPS are outside the scope of the CY 2022 OPPS/ASC proposed rule. Accordingly, we are not revising the existing codes for CAR T-cell therapies to remove leukapheresis and dose preparation procedures, and we are not accepting the recommendations at this time to revise the status indicators for procedures described by CPT codes 0537T, 0538T, and 0539T. We will continue to evaluate and monitor payment for CAR T-cell therapies.

In summary, after consideration of the public comments we received, we are finalizing our proposal to assign status indicator ''B'' to CPT codes 0537T, 0538T, and 0539T for CY 2022. Additionally, we are continuing our policy from CY 2019 to assign status indicator ''S'' to CPT code 0540T for CY 2022. Table 25 below shows the final SI and APC assignments for HCPCS codes 0537T, 0538T, 0539T, and 0540T for CY 2022. For more information on CY 2022 OPPS final status indicators, APC assignments, and payment rates for HCPCS codes, including the CAR T-cell drug codes, we refer readers to Addendum B to this final rule with comment period. In addition, the status indicator definitions can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2022) to this final rule with comment period. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 25: CAR T-CELL THERAPY PREPARATION AND ADMINISTRATION FINAL SI AND APC ASSIGNMENT FOR CPT CODES 0537T, 0538T, 0539T, AND 0540T FOR CY 2022

CPT Code	Long Descriptors	Proposed CY 2022 SI	Final CY 2022 SI	Final CY 2022 APC
0537T	Chimeric antigen receptor t-cell (car-t) therapy; harvesting of blood-derived t lymphocytes for development of genetically modified autologous car-t cells, per day	B	B	N/A
0538T	Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (eg, cryopreservation, storage)	B	B	N/A
0539T	Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration	B	B	N/A
0540T	Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous	S	S	5694

10. ClariFix Procedure (APC 5164)

For CY 2022, we proposed to continue to assign HCPCS code C9771 (Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral)) to APC 5164 Level 4 ENT Procedures. We created HCPCS code C9771 to describe the technology associated with nasal endoscopy with cryoablation of nasal tissues and/or nerves, based on our review of a New Technology APC application submitted by the manufacturer of the technology. HCPCS code C9771 was effective on January 1, 2021.

Comment: We received one comment from the manufacturer requesting that HCPCS code C9771 be reassigned to APC 5165 Level 5 ENT Procedures, which had a proposed CY 2022 OPPS payment rate of $5,218.17. The commenter believed that assigning HCPCS code C9771 to APC 5165 would be more appropriate due to the resource and clinical similarity to the procedures in that APC.

Response: We thank the commenter for their recommendation. After reviewing the comment, and after further evaluation of the procedure, as well as input from our medical advisors, we continue to believe that the current APC assignment for HCPCS code C9771 is appropriate, based on its resource and clinical similarity to the procedures in APC 5164. Therefore, we are not accepting the commenter's recommendation. We remind hospitals that every year we review the APC assignments for all services and items paid under the OPPS. We will reassess the APC assignment for the procedure described by HCPCS C9771 once we have claims data for the code. We note that the first year that claims data will be available for HCPCS code C9771 will be during the CY 2023 rulemaking cycle.

In summary, after consideration of the public comment, we are finalizing our proposal without modification. The final CY 2022 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

11. Dilapan-S Cervical Dilation Procedure (APC 5412)

For CY 2022, we proposed to continue to assign CPT code 59200 (Insertion of cervical dilator (for example, laminaria, prostaglandin) (separate procedure)) to APC 5412 (Level 2 Gynecologic Procedures) with a proposed payment rate of $289.30.

Comment: A few commenters requested that CMS reassign CPT code 59200 to APC 5413 (Level 3 Gynecologic Procedures) with a proposed payment rate of $650.81. These commenters state that the cost of Dilapan-S, a cervical softening and dilation device, is not reflected in the payment rate for APC 5412.

Response: For CY 2022, OPPS payments are based on claims submitted between January 1, 2019, through December 31, 2019, that were processed on or before June 30, 2020. Based on our evaluation of the claims data for this final rule with comment period, the geometric mean cost for CPT code 59200 is $456.73, which, while it does fall outside the range of geometric mean costs for APC 5412 ($206.24–$402.55) it does not fall within the range of geometric mean costs for APC 5413 ($516.27–$874.50.) Given that the Dilapan-S device and CPT code 59200 have both existed for a significant period of time, the fact that payment for CPT code 59200 does not reflect the costs of Dilapan-S suggests that this device is not routinely used to furnish CPT code 59200. Furthermore, based on our review of the clinical characteristics of the procedure and input from our medical advisors, we continue to believe that CPT code 59200 is more clinically similar to the other services in APC 5412.

In summary, after consideration of the public comments, we are finalizing our proposal to continue to assign CPT code 59200 to APC 5412. The final CY 2022 OPPS payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

12. Ellipsys System Hemodialysis Arteriovenous Fistula (AVF) Procedure (APC 5194)

For CY 2022, we proposed to continue to assign HCPCS code G2170 to APC 5194 (Level 4 Endovascular Procedures) with a proposed payment rate of $16,484.41.

Comment: Commenters supported this proposal.

Response: We appreciate commenters' support.

In summary, after consideration of the public comments, we are finalizing our proposal without modification. Specifically, we are finalizing our APC proposal to continue to assign HCPCS code G2170 to APC 5194.

The final CY 2022 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

13. Esophagogastroduodenoscopy (APC 5331)

For CY 2022, we proposed to continue to assign CPT code 43240 (Esophagogastroduodenoscopy, flexible, transoral; with transmural drainage of pseudocyst (includes placement of transmural drainage catheter[s]/stent[s], when performed, and endoscopic ultrasound, when performed)) to APC 5303 (Level 3 Upper GI Procedures) with a proposed payment rate of $3,160.76.

Comment: One commenter requested the reassignment of CPT code 43240 to APC 5331 (Complex GI Procedures) with a proposed payment rate of $5,159.81. The commenter stated that the geometric mean cost of CPT code 43240 ($5827.94) exceeds the 2 times threshold for APC 5303 and is within the range of the geometric mean costs for APC 5331 ($4,706.48–$6,277.12). Furthermore, the commenter stated that CPT code 43240 is more clinically similar to the services in APC 5331, which includes all other gastroenterology stent placement codes.

Response: Based on our review of the cost data and input from our clinical advisors, we agree that CPT code 43240 would be more appropriately placed in APC 5331 based on its clinical and resource homogeneity to the procedures in the APC. Therefore, we are reassigning CPT code 43240 to APC 5331.

In summary, after consideration of the public comments, we are finalizing the reassignment of CPT code 43240 to APC 5331. The final CY 2022 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

14. External Electrocardiogram (ECG) (APCs 5733 and 5734)

For CY 2022, we proposed to continue to assign CPT code 93242 (External ECG recording for more than 48 hours up to 7 days by continuous rhythm recording) to APC 5732 (Level 2 Minor Procedures) with a proposed payment rate of $34.72 and CPT code 93243 (External ECG recording for more than 48 hours up to 7 days scanning analysis with report) to APC 5733 (Level 3 Minor Procedures) with a proposed payment rate of $57.12.

Comment: A few commenters suggested that, based on clinical similarity to CPT codes 93225 (External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)) and 93226 (External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report), which include payment for a holter monitor, CMS should reassign CPT codes 93242 and 93243 to APC 5734 (Level 4 Minor Procedures) with a proposed payment rate of $115.71. Commenters further stated that placement in APC 5734 would be consistent with the placement of the predecessor codes, CPT codes 0296T (External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; recording (includes connection and initial recording)) and 0296T (External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report).

Response: Based on our review of the clinical characteristics of the procedure and input from our medical advisors, we agree with commenters that resources associated with furnishing CPT codes 93242 and 93243 may not be accurately reflected in their current APC assignment. We do not agree with commenters that both codes should be reassigned to APC 5734. We note that the predecessor codes, CPT codes 0296T and 0297T, described 21 days of continuous monitoring, while the current codes, CPT codes 93242 and 93243, describe 7 days of monitoring. We believe that CPT code 93242 shares greater clinical and cost similarities to the services in APC 5733 (Level 3 Minor Procedures), which has a proposed payment rate of $57.12. We agree with commenters, however, the CPT code 93243 does share clinical and cost similarities with the other services in APC 5734.

In summary, after consideration of the public comments, we are finalizing our proposal with modification. Specifically, we are assigning CPT code 93242 to APC 5733 and CPT code 93243 to APC 5734. The final CY 2022 OPPS payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

15. Eye-Movement Analysis Without Spatial Calibration (CPT Code 0615T)

The CPT Editorial Panel established a new CPT code 0615T, effective July 1, 2020, to describe eye-movement analysis without spatial calibration that involves the use of the EyeBOX system as an aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI). The EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion within one week of head injury in patients 5 through 67 years of age in conjunction with a standard neurological assessment of concussion. A negative EyeBOX classification may correspond to eye movement that is consistent with a lack of concussion. A positive EyeBOX classification corresponds to eye movement that may be present in both patients with or without a concussion.

We included this new code in the July quarterly OPPS update CR (Transmittal 10224, Change Request 11814, dated July 15, 2020). Effective July 1, 2020, we assigned CPT code 0615T to APC 5734 (Level 4 Minor Procedures) with status indicator ''Q1'' (conditionally packaged).

As displayed in the Addendum B to the CY 2022 ASC/OPPS proposed rule, we proposed to continue to assign 0615T to APC 5734 with status indicator ''Q1'' and a proposed OPPS payment rate of $115.71 for CY 2022.

Comment: The manufacturer of the EyeBOX resubmitted their comment again this year because they are still concerned that the lack of adequate, separate reimbursement will strongly discourage hospitals from providing this important technology to their patients.

The commenter urged CMS to: (1) Change the APC assignment of CPT code 0615T to APC 5722 (Level 2 Diagnostic Tests and Related Services); and (2) change the status indicator for the service to ''S'' to allow for separate payment under the OPPS. The commenter continues to claim that the proposed reimbursement rate for services in APC 5734 is inadequate to pay hospitals appropriately for the costs of furnishing the EyeBOX test. They assert the EyeBOX test costs hospitals at least $200.00 to provide and the clinical characteristics and resources associated with 0615T are more similar to codes in APC 5722 than services in APC 5734.

Response: We note that OPPS payment rates for the CY 2022 final rule are based on claims submitted between January 1, 2019, through December 31, 2019, that were processed on or before June 30, 2020. Because HCPCS code 0615T was established on July 1, 2020, we did not have claims data available for CY 2022 OPPS ratesetting.

As far as the resource similarity of CPT code 0615T to other eye-related diagnostic tests that are assigned to APC 5722, such as CPT code 92240 (Indocyanine-green angiography (includes multiframe imaging) with interpretation and report, unilateral or bilateral) and CPT code 92242 (Fluorescein angiography and indocyanine-green angiography (includes multiframe imaging) performed at the same patient encounter with interpretation and report, unilateral or bilateral), the EyeBOX test does not involve an injection. Therefore, we continue to believe that the resource costs for CPT code 0615T are not comparable to other eye-related diagnostic tests in APC 5722. Updated CY 2019 claims data for this final rule with comment period indicate that the geometric mean cost of APC 5722 is 257.89, while the geometric mean cost of APC 5734 is $109.88. Based on the lack of claims data, we believe that maintaining assignment of APC 5734 for CPT code 0615T for CY 2022 continues to be appropriate.

Depending on the procedures submitted on the claim, and whether the procedure described by CPT code 0615T is performed with any other services on the same day, the procedure described by CPT code 0615T may be paid separately through an APC (in this case APC 5734) or receive packaged payment when accompanying a more significant procedure that is reported on the claim. Based on the nature of this procedure, which may be performed by itself or with other procedures on the same claim, we believe that the continued assignment of status indicator ''Q1'' is appropriate for the procedure described by CPT code 0615T.

As we do every year, we will reevaluate the APC assignment for CPT code 0615T for the next rulemaking cycle. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

We are finalizing our proposal, without modification, to continue to assign CPT code 0615T to status indicator ''Q1'' and APC 5734 for CY 2022. The final CY 2022 payment rate for the CPT code can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

16. FemSelect Enplace Procedure (APC 5415)

For CY 2022, we proposed to continue to assign HCPCS code C9778 (Colpopexy, vaginal; minimally invasive extra-peritoneal approach (sacrospinous)) to APC 5414 Level 4 Gynecologic Procedures. We created HCPCS code C9778 to describe the technology associated with vaginal colpopexy by sacrospinous ligament fixation, based on our review of a New Technology APC application submitted by the manufacturer of the technology. HCPCS code C9778 was effective on July 1, 2021.

Comment: We received many comments from providers and the manufacturer requesting that HCPCS code C9778 be reassigned to APC 5415 Level 5 Gynecologic Procedures, which had a proposed CY 2022 OPPS payment rate of $4,525.49. Commenters stated that the resource cost exceeded the payment provided by APC 5414, and that APC 5415 would be a more appropriate APC assignment.

Response: We thank the commenters for their recommendations. Based on input from our medical advisors, further evaluation of the resources to perform the surgery, and its similarity to existing procedures, we believe that HCPCS code C9778 should be reassigned to APC 5415. Based on our assessment, we believe that the service described by HCPCS code C9778 shares similar resource and clinical characteristics to the procedures included in APC 5415.

In summary, after consideration of the public comments, we are reassigning HCPCS code C9778 to APC 5415 Level 5 Gynecologic Procedures for CY 2022, as shown in Table 26 below. The final CY 2022 OPPS payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

As we do every year, we will reevaluate the APC assignment for HCPCS code C9778 for the next rulemaking cycle. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS. The first year that claims data will be available for HCPCS code C9778 will be during the CY 2023 rulemaking cycle.

TABLE 26: PROPOSED AND FINAL APC ASSIGNMENT FOR HCPCS CODE C9778

HCPCS Code	Long Descriptor	Proposed CY 2022 APC	Final CY 2022 APC
C9778	Colpopexy, vaginal; minimally invasive extra-peritoneal approach (sacrospinous)	5414	5415

17. Hypoglossal Nerve Neurostimulator (HGNS) Procedure (APC 5465)

Effective January 1, 2022, the AMA's CPT Editorial Panel created a new code to describe open implantation of hypoglossal nerve neurostimulator array. For CY 2022, we proposed to assign CPT code 64582 to APC 5465 (Level 5 Neurostimulator and Related Procedures) with a proposed payment rate of $30,208.51. We note that CPT code 64582 was listed as placeholder code 645X1 in OPPS Addendum B of the CY 2022 OPPS/ASC proposed rule.

Comment: One commenter expressed support for the proposed APC assignment.

Response: We thank the commenter for their support.

In summary, after consideration of the public comments, we are finalizing our proposal without modification. Specifically, we are finalizing our APC proposal to assign CPT code 64582 to APC 5465. The final CY 2022 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

18. IDx-DR: Artificial Intelligence System To Detect Diabetic Retinopathy (APC 5733)

For CY 2022, we proposed to continue to assign CPT code 92229 (Imaging of retina for detection or monitoring of disease; with point-of care automated analysis with diagnostic report; unilateral or bilateral) to APC 5733 (Level 3 Minor Procedures) with a proposed payment rate of $57.12.

Comment: Some commenters disagreed with the proposed payment amount and requested a revision in the assignment from APC 5733 to APC 5734 (Level 4 Minor Procedures) with a proposed payment rate of $115.71. The commenters reported that the service described by CPT code 92229 is similar to the technical components described by existing CPT code 92250 (Fundus photography with interpretation and report), which was proposed for assignment to APC 5734. They stated that providers previously billed for this service on an interim basis under CPT code 92250. The commenters indicated that APC 5734, which is the APC assigned to the predecessor CPT code 92250, is the more appropriate assignment for CPT code 92229 until sufficient Medicare claims data can be collected by CMS to either retain that assignment or reassign to another APC.

One commenter expressed support for our proposal to continue APC assignment of CPT code 92229 to APC 5733.

Response: As discussed in the CY 2021 OPPS final rule with comment period (85 FR 85962), we do not believe that CPT code 92250, which the commenters reported to be the predecessor code, is similar to the IDx–DR test; otherwise, the placement of the new IDx–DR code would have been close to CPT code 92250. As the commenter did not provide any additional clinical information or cost data, we continue to believe that CPT code 92229 should be assigned to APC 5733.

In summary, after consideration of the public comments, we are finalizing our proposal without modification. Specifically, we are continuing to assign CPT code 92229 to APC 5733. The final CY 2022 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

19. Intravascular Lithotripsy (IVL) Procedure (APCs 5193 and 5194)

As explained in the CY 2021 OPPS/ASC final rule with comment period, we finalized our proposal to assign HCPCS codes C9764 (Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed) and C9765 (Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed) to APC 5192 and C9766 (Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed) to APC 5193 (85 FR 85975 through 85976). For a detailed discussion on the APC assignments for HCPCS code(s) describing the IVL procedures, we refer readers to the CY 2021 OPPS/ASC final rule with comment period (85 FR 85975 through 85976).

At the August 23, 2021 meeting, the HOP Panel recommended that CMS reassign HCPCS code C9764 to APC 5193 and HCPCS codes C9765 and C9766 to APC 5194, as long as the cost of the IVL device is within 10 percent of other devices currently available.

Comment: Several commenters, including the manufacturer, disagreed with CMS's proposed CY 2022 APC assignments for the IVL service described by HCPCS codes C9764, C9765, and C9766. They argued that, for new procedures that did not have claims in the CY 2019 claims data, current claims data should be used when reviewing for APC placement. The commenter also noted the CY 2020 claims data provided evidence to support their argument that the service described by HCPCS code C9764 is not adequately reimbursed under APC 5192, and recommended reassignment to APC 5193 (Level 3 Endovascular Procedures). Similarly, the commenters indicated that assignment of HCPCS codes C9765 and C9766 to APC 5193 does not provide adequate payment for the service based on 2020 claims data and that those codes should instead be placed in APC 5194 (Level 4 Endovascular Procedures).

Response: In the CY 2022 OPPS/ASC proposed rule, we proposed to use 2019 claims data in the OPPS due to the effects of the PHE on the CY 2020 claims data. As the commenter noted, claims data are not available for HCPCS codes C9764 through C9766 in the CY 2019 claims data, only in CY 2020. As discussed in more detail in section X.E. of this final rule with comment period, we are not using CY 2020 claims data for ratesetting because of data integrity concerns with respect to the broader OPPS; however, based on stakeholder request, we are reviewing the CY 2020 claims data for determining potential APC assignments in cases where CY 2019 claims data did not include any information on new procedures.

Under what would otherwise be the standard ratesetting process, we would typically use CY 2020 claims data submitted for services furnished in CY 2020, that were processed on or before June 30, 2021. Our analysis of that CY 2020 claims data supports reassigning CPT code C9764 to APC 5193 and CPT codes C9765 and C9766 to APC 5194, based on their estimated geometric mean costs. Specifically, our claims data show a geometric mean cost of approximately $11,442.47 for HCPCS code C9764 based on 253 single claims, which is comparable to the geometric mean cost of about $10,258.49 for APC 5193, rather than the geometric mean cost of approximately $5,061.89 for APC 5192. The geometric mean cost of approximately $17,372.02 for HCPCS code C9765 and the geometric mean

cost of approximately $19,285.11 for HCPCS code C9766 is also consistent with the costs for significant services in APC 5194, which range between about $10,670.16 (for HCPCS code C9754) to $24,311.10 (for HCPCS code C9767). Based on our analysis of the latest available CY 2020 claims data, we believe that HCPCS codes C9765 and C9766 are more appropriately assigned to APC 5194.

In summary, after consideration of the public comments, we are assigning HCPCS code C9764 to APC 5193 and HCPCS codes C9765 and C9766 to APC 5194. Table 27 below lists the three HCPCS codes for the IVL procedure and their APC and SI assignments for CY 2022. The final CY 2022 OPPS payment rates for the codes can be found in Addendum B of this final rule with comment period. Addendum B is available via the internet on the CMS website.

TABLE 27: FINAL SI AND APC ASSIGNMENT FOR HCPCS CODES C9764 THROUGH C9766

HCPCS Code	Long Descriptor	Final OPPS SI	Final OPPS APC
C9764	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed	J1	5193
C9765	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	J1	5194
C9766	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed	J1	5194

20. Lixelle Apheresis

Lixelle β2-microglobulin Apheresis Column is indicated for use in the treatment of dialysis-related amyloidosis (DRA), a disease that affects people with end-stage renal disease (ESRD). DRA is a metabolic disorder from the failure of the kidney to filter and remove β2-microglobulin, typically from chronic hemodialysis (typically 5 years or longer). The Lixelle device is used in an apheresis procedure that selectively removes β2-microglobulin from circulating blood and used pursuant to a physician prescription in conjunction with hemodialysis. It is intended to be used at each hemodialysis session (that is, frequency of treatment is expected to be 3 times per week). In March 2015, FDA approved LIXELLE® as a Class III Humanitarian Use Device (HUD) with an approved Humanitarian Device Exemption (HDE). There are currently no specific HCPCS or CPT code that represent the Lixelle service.

Comment: Two commenters, including the manufacturer of Lixelle apheresis column, requested payment for the procedure under the OPPS. One commenter stated that Lixelle is the only device available for the treatment DRA and that all DRA patients are Medicare beneficiaries. The commenter stated that they have been unable to complete the FDA-required post-approval study as a condition of the HDE, due to difficulty in securing patient enrollment because of lack of CMS payment for the Lixelle apheresis procedure. The commenter stated that CMS should rely upon the HUD program requirements and post-approval clinical studies mandated and approved by FDA for coverage and payment of Lixelle apheresis in the OPPS. The commenter acknowledged that Medicare payment under the ESRD PPS is not possible at this time but stated that payment under the OPPS may be more clinically appropriate. The commenter requested that CMS provide payment under the OPPS because the Lixelle apheresis is not eligible for Medicare payment when furnished in the dialysis facility at this time, and therefore, these treatments (even though technically not ''scheduled'' or ''non-routine'') should be eligible for payment when furnished in the hospital outpatient department under the OPPS. Specifically, the commenter requested that CMS provide payment under the OPPS using the following pathways: (1) By paying for the apheresis procedure used with the Lixelle device through CPT code 36516 (Therapeutic apheresis with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion), proposed to be assigned to APC 5243 (Level 3 Blood Product Exchange and Related Services) for CY 2022, and requiring the use of a modifier or add-on code when the Lixelle apheresis procedure is billed to reduce the payment for the procedure to the payment rate for APC 5242 (Level 2 Blood Product Exchange and Related Services); (2) by allowing payment for

the dialysis performed as part of Lixelle apheresis procedure through HCPCS code G0257 (Unscheduled or emergency dialysis treatment for an ESRD patient in a hospital outpatient department that is not certified as an ESRD facility), which is assigned to APC 5401 (Dialysis) for CY 2022, and requiring the use of a modifier or add-on code to provide additional payment beyond that provided for APC 5401; or (3) by creating a HCPCS C code or G code for the Lixelle apheresis procedure and assigning the code to APC 5242 (Level 2 Blood Product Exchange and Related Services).

Response: We appreciate the commenters' input on the Lixelle device and will consider their recommendations for future rulemaking.

21. Low Dose Computed Tomography (LDCT) (APC 5522)

For CY 2022, we proposed to continue to assign CPT code 71271 (Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)) to APC 5521 (Level 1 Imaging without Contrast) with a proposed payment rate of $83.01.

Comment: Several commenters stated that CPT code 71271 should be reassigned to APC 5523 (Level 3 Imaging without Contrast) with a proposed payment rate of $236.14. These commenters stated that CPT code 71271 should not be in a lower APC than CPT code 71270 (Computed tomography, thorax; without contrast material, followed by contrast material(s) and further sections) given that CPT code 71271 has additional resource costs, such as greater clinical staff time. The commenter noted that we proposed to assign CPT code 71270 to APC 5571 (Level 1 Imaging With Contrast) with a payment rate of $183.30.

Response: The predecessor code to CPT code 71271 was HCPCS code G0297 (Low dose ct (ldct) scan for lung cancer screening) which was assigned to APC 5521. However, in the CY 2021 Physician Fee Schedule final rule, we stated that it was a longstanding CMS policy that the payment for HCPCS code G0297 match the payment rate for CPT code 71250, which we proposed to assign to APC 5522 (Level 2 Imaging without Contrast) with a payment rate of $111.73, as the services are almost identical in terms of clinical similarity and resource costs (85 FR 84621 through 84622). In the interests of preserving the relationship between the predecessor code and CPT code 71250, and based on our review of the clinical characteristics of the procedure and input from our medical advisors, we believe that CPT code 71271 should be reassigned to APC 5522 (Level 2 Imaging without Contrast). We believe that assignment to APC 5522 for both CPT codes 71250 and 71271 accurately reflects the resources associated with performing this service.

In summary, after consideration of the public comments, we are finalizing our proposal, with modification. Specifically, we are reassigning CPT code 71271 to APC 5522. The final CY 2022 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

22. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APC 5463)

CPT code 0398T (Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) describes MRgFUS procedures for the treatment of essential tremor. We have identified 175 paid claims for CY 2019 with a geometric mean of $12,334.67. CPT code 0398T had been assigned to a New Technology APC for several years. Then, in CY 2021, we reorganized the Neurostimulator and Related Procedures APCs to add a new Level 3 category (APC 5463) that had a geometric mean of approximately $10,950. While the payment rate for APC 5463 was somewhat lower than the geometric mean of CPT code 0398T, it was a reasonable estimate of the cost of MRgFUS for the treatment of essential tremor in a prospective payment system where some services receive more payment than their geometric mean cost, while other services receive less payment than their geometric mean cost. For CY 2022, we proposed continuing to assign CPT code 0398T to APC 5463 with a payment rate of approximately $10,956.33.

Comment: One commenter, the manufacturer, requests a higher paying APC for CPT code 0398T because the current payment rate for APC 5463 (Level 3 Neurostimulator and Related Procedures) of approximately $10,956.33 is substantially lower than the geometric mean cost of the service. According to the commenter, the geometric mean of CPT code 0398T has steadily increased from $10,136 in CY 2018 to $13,907 in CY 2020.

Response: We appreciate the commenter's concerns about the level of payment for CPT code 0398T. However, the OPPS is a prospective payment system and it is expected that any individual service may be paid more or less than the geometric mean cost of the service. The current payment difference between the geometric mean cost of CPT code 0398T and the payment rate for APC 5463 is $1,153.66 ($12,109.99 minus $10,956.33) with the payment rate of APC 5463 equal to $10,956.33. That means there is no violation of the two-times rule to assign CPT code 0398T to APC 5463, and the service is assigned to an APC that covers around 90 percent of the geometric mean cost of the service. Also, CPT code 0398T is grouped with other neurostimulator and related procedures that have clinical and resource similarity to the MRgFUS.

After our review of the public comments, we have decided to implement our proposal without modification to continue to assign CPT code 0398T to APC 5463 (Level 3 Neurostimulator and Related Procedures). The final CY 2022 payment rate for CPT code 0398T can be found in Addendum B to this final rule with comment period, which is available via the internet on the CMS website.

23. Medical Physics Dose (APC 5612)

For CY 2022, we proposed to continue to assign CPT code 76145 (Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report (medical physicist/dosimetrist)) in APC 5611 (Level 1 Therapeutic Radiation Treatment Preparation) with a proposed payment rate of $130.19.

Comment: Several commenters disagreed with the assignment to APC 5611 and requested a reassignment to APC 5724 (Level 4 Diagnostic Tests and Related Services) with a proposed payment rate of $943.96. The commenters stated that the services assigned to APC 5724 require similar resource use as CPT code 76145. Commenters also stated that APC 5724 contains a range of services that are clinically similar to CPT 76145.

Response: Given that we have no claims data for this service, and that APC 5724 does not contain any radiation oncology services, we do not believe that APC 5724 is an appropriate assignment on the basis of clinical similarity or similar costs. However, based on our review of the service associated with CPT code 76145 and input from our medical advisors, we believe that APC code 5612, with a proposed payment rate of $347.44, may be a more appropriate assignment for

the code. APC 5612 contains CPT code 77307 (Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s)), which is clinically similar to CPT code 76145 in that CPT code 77307 describes the work of a medical physicist and dosimetrist. Once we have claims data, we will review the APC assignment and determine whether a change is necessary. We note that we review, on an annual basis, the APC assignments for all items and services paid under the OPPS.

In summary, after consideration of the public comments, we are reassigning CPT code 76145 to APC 5612. The final CY 2022 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

24. MiVu Mucosal Integrity Testing System (APC 5303)

For CY 2022, we proposed to continue to assign HCPCS code C9777 (Esophageal mucosal integrity testing by electrical impedance, transoral (list separately in addition to code for primary procedure)) to OPPS status indicator ''N,'' to indicate that the payment for HCPCS code C9777 is packaged into the payment for the primary procedure. We created HCPCS code C9777 to describe mucosal integrity testing by electrical impedance, based on our review of a New Technology APC application submitted by the manufacturer of the technology. HCPCS code C9777 was effective on April 1, 2021. Based on the application submitted to CMS and our initial review of the procedure, we believed the MiVu test to be performed with another primary procedure on the same day. Because the MiVu test is always performed as an add-on test to either an esophagoscopy or esophagogastroduodenoscopy, we established a C-code to appropriately describe the add-on component. Under the regulation at 42 CFR 419.2, payment for add-on codes is packaged or conditionally packaged into the payment for the related procedures or services under the OPPS.

Comment: We received several comments from providers and the manufacturer requesting that HCPCS code C9777 be separately reimbursed and reassigned to APC 5303 Level 3 Upper GI Procedures, which had a proposed CY 2022 OPPS payment rate of $3,160.76. Commenters argued that MiVu™ should be considered the primary procedure, not the esophagoscopy or esophagogastroduodenoscopy and that based on the cost of the device and procedure, the appropriate APC assignment is APC 5303.

Response: We thank the commenters for their recommendations. After further evaluation of procedures performed in conjunction with the MiVu test on the same day, review of the comments, and input from our medical advisors, we believe that modifying the descriptor for the C-code is appropriate. We believe that revising the long descriptor to describe the service of performing both the MiVu test with either an esophagoscopy or esophagogastroduodenoscopy on the same day would ensure accurate tracking and reporting of the service and minimize inappropriate reporting of the services. Consequently, effective January 1, 2022, we are revising the descriptor for HCPCS code C9777 to read ''Esophageal mucosal integrity testing by electrical impedance, transoral, includes esophagoscopy or esophagogastroduodenoscopy,'' to accurately reflect how the procedure is currently performed in the hospital outpatient setting. With the change in the descriptor for HCPCS code C9777, we are assigning HCPCS code C9777 to APC 5303 based on its resource and clinical homogeneity to the other procedures in the APC. We remind hospitals that because HCPCS code C9777 describes both the MiVu test performed with either an esophagoscopy or esophagogastroduodenoscopy on the same day, HOPDs should not report separate HCPCS codes for the esophagoscopy or esophagogastroduodenoscopy.

In summary, after consideration of the public comments, we are modifying the long descriptor for HCPCS code C9777, as shown in Table 28 below, and reassigning HCPCS code C9777 to APC 5303 (Level 3 Upper GI Procedures) for CY 2022. The final CY 2022 OPPS payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

As we do every year, we will reevaluate the APC assignment for HCPCS code C9777 for the next rulemaking cycle. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

TABLE 28: PROPOSED AND FINAL CY 2022 SI AND APC ASSIGNMENT FOR HCPCS CODE C9777

HCPCS Code	Long Descriptor	Proposed CY 2022 SI	Final CY 2022 SI	Final CY 2022 APC
C9777	Esophageal mucosal integrity testing by electrical impedance, transoral, includes esophagoscopy or esophagogastroduodenoscopy	N	J1	5303

25. Musculoskeletal Procedures (APCs 5111 Through 5116)

Prior to the CY 2016 OPPS, payment for musculoskeletal procedures was primarily divided according to anatomy and the type of musculoskeletal procedure. As part of the CY 2016 reorganization to better structure the OPPS payments to utilize prospective payment packages, we consolidated these individual APCs so that they became a general Musculoskeletal APC series (80 FR 70397 through 70398).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59300), we continued to apply a six-level structure for the Musculoskeletal APCs because doing so provided an appropriate distinction for resource costs at each level and provided clinical homogeneity. However, we indicated that we would continue to review the structure of these APCs to determine whether additional granularity would be necessary.

In the CY 2019 OPPS proposed rule (83 FR 37096), we recognized that commenters had previously expressed concerns regarding the granularity of the current APC levels and, therefore, requested comment on the establishment of additional levels. Specifically, we solicited comments on the creation of a new APC level between the current Level 5 and Level 6 within the Musculoskeletal APC series. While some commenters suggested APC reconfigurations and requests for change to APC assignments, many commenters requested that we maintain the current six-level structure and continue to monitor the claims data as they become available. Therefore, in the CY 2019 OPPS/ASC final rule with comment period, we maintained the six-level APC structure for the Musculoskeletal Procedures APCs (83 FR 58920 through 58921).

Based on the claims data available for the CY 2022 OPPS/ASC proposed rule, we continued to believe that the six-level APC structure for the Musculoskeletal Procedures APC series is appropriate and we proposed to maintain the it for the CY 2022 OPPS update.

Comment: One commenter requested that we assign CPT code 28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method) and CPT code 28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint) from APC 5114 to APC 5115. They noted that if these codes were considered cost significant for purposes of the 2 times rule, then these codes would cause 2 times rule violations in APC 5114.

Response: We appreciate the commenter's recommendation regarding the APC assignment of CPT 28297 and 28740. CPT codes 28297 and 28740 are currently assigned to APC 5114 (Level 4 Musculoskeletal Procedures). We note that APC 5114 does not currently have a 2 times rule violation, under the requirements for cost significance as described in section III.B.2. of this final rule with comment period. In addition, we have reviewed the codes' geometric mean cost in both the CY 2019 and CY 2020 claims data available as well as their clinical similarity to other codes within APC 5114 and believe that their current APC assignment continues to be appropriate.

Comment: One commenter supported the proposed assignment of HCPCS code 0627T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level) and HCPCS code 0629T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with ct guidance, lumbar; first level) to APC 5115. Another commenter supported the proposed assignment of HCPCS code 0627T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level) and 0630T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with ct guidance, lumbar; each additional level (list separately in addition to code for primary procedure)) to APC 5115.

Response: We appreciate the commenters' support. We note that that the availability of these codes does not mean that the product(s) are legally marketed under the Federal Food, Drug and Cosmetic Act and/or the Public Health Service Act.

Comment: A commenter requested that we allow an exception from the broader proposed OPPS ratesetting process to use the CY 2020 claims data for ratesetting for the musculoskeletal APC series (5111 through 5116). Two commenters also requested that we allow an exception for the use of CY 2020 claims data for CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft), which was removed from the IPO list beginning in CY 2020.

Response: We appreciate the commenters' concerns regarding available data and its use in OPPS ratesetting. However, we note that widespread use of claims data from two different years to set rates for a items and services in a single year could distort the OPPS relative payment weights, which we believe would be inappropriate and unnecessary when claims data from a single year—in this case, 2019—are largely available for ratesetting and using these data generally to set CY 2022 rates allows us to avoid this sort of distortion. As a result, we are establishing a final policy of using CY 2019 claims for establishing the OPPS relative weights but allowing limited use of CY 2020 claims for informational purposes where CY 2019 claims are not otherwise available. For additional detail regarding the use of CY 2019 claims in CY 2022 OPPS ratesetting, please see section X.E. of this final rule with comment period.

After consideration of the comments, we are finalizing the proposed assignment of CPT codes 28297 and 28740 to APC 5114, and the proposed assignment of CPT codes 0627T, 0629T and 0630T to APC 5115 for the CY 2022 OPPS.

26. Non-Highly Enriched Uranium (Non-HEU) Sources (APC 1442)

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Some of the Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, is produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States would like to eliminate domestic reliance on these reactors, and is promoting the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc99m without HEU are technologically and economically viable, and conversion to such production has begun. We expect that this change in the supply source for the radioisotope used for modern medical imaging will introduce new costs into the payment system that are not accounted for in the historical claims data.

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study

dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68321).

Comment: Multiple commenters requested that we increase the payment rate for HCPCS add-on code Q9969 from $10 and to make the add-on code permanent. The commenters noted that we have not increased the payment rate for Q9969 since the code was established in CY 2013, and one of the commenters believes that we have made only token efforts to promote the use of non-HEU produced Mo-99, the parent nuclide to Tc-99m.

One of the commenters supported a rate increase to Q9969 to fully reflect the additional cost to providers to obtain non-HEU medical isotopes. The same commenter suggested that if such a cost-analysis could not be done for CY 2022, we should increase the payment for Q9969 by the annual market basket increase for CY 2022 along with a one-time increase to reflect prior increases to the market basket between CY 2013 and CY 2021. Alternatively, the commenter suggested the payment rate could be increased by the change in the drug cost threshold packaging amount between CY 2013 and CY 2022.

Response: We appreciate the information we received from the commenters supporting an increase to the payment rate of $10 for HCPCS code Q9969, especially since the conversion to non-HEU sources for medical isotopes has not been completed by all producers. As discussed in the CY 2013 OPPS/ASC final rule with comment period, we did not finalize a policy to use the usual OPPS methodologies to update the non-HEU add-on payment (77 FR 68317). The purpose of the additional payment is limited to mitigating any adverse impact of transitioning to non-HEU sources, and we believe the add-on is appropriate at this time.

Comment: Multiple commenters supported the current payment amount for HCPCS code Q9969, and they requested that we finalize our proposed payment rate for the add-on.

Response: We appreciate the support of the commenters for the proposed payment rate for HCPCS code Q9969.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue the policy of providing an additional $10 payment for radioisotopes produced by non-HEU sources for CY 2022 as represented by HCPCS code Q9969.

27. Nuclear Medicine Services: Single-Photon Emission Computed Tomography (SPECT) Studies (APC 5593)

For CY 2022, we proposed to continue to assign CPT code 78803 (Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (spect), single area (eg, head, neck, chest, pelvis), single day imaging)) to APC 5593 (Level 3 Nuclear Medicine and Related Services) with a proposed payment rate of $1,340.84.

Comment: One commenter expressed support for the proposed APC assignment.

Response: We thank the commenter for their support. We note that, based on our analysis of the claims data for this CY 2022 OPPS/ASC final rule with comment period, our data reveals a geometric mean cost of about $529.69 based on 4157 single claims (out of 9451 total claims), which is in line with the geometric mean cost of $1,273.36 for APC 5593.

In summary, after consideration of the public comments, we are finalizing our proposal without modification to assign CPT code 78803 to APC 5593. The final CY 2022 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

28. Pathogen Test(s) for Platelets (APC 5733)

For the July 2017 update, the HCPCS Workgroup established HCPCS code Q9987 (Pathogen(s) test for platelets) effective July 1, 2017. This new code and the OPPS APC assignment was announced in the July 2017 OPPS quarterly update CR (Transmittal 3783, Change Request 10122, dated May 26, 2017). Subsequently, HCPCS code Q9987 was deleted on December 31, 2017, and replaced with permanent HCPCS code P9100 (Pathogen(s) test for platelets) effective January 1, 2018. Each of the HCPCS codes were assigned to New Technology APCs for the period of July 2017 through December 2020 with payment rates for the service ranging between $25.50 and $35.50. Starting in January 2021, we decided to assign P9100 to APC 5732 (Level 2 Minor Procedures) with a payment rate of approximately $33.

From July 2017 until 2021, only one type of pathogen test for platelets, rapid bacterial testing, was described by HCPCS code P9100. The estimated cost for a rapid bacterial test was around $30, which has been confirmed through claims data. Starting in 2021, a new type of pathogen test for platelets, culture-based bacterial testing, using large volume delayed sampling (LVDS), was introduced. This culture-based method is used to test for bacterial contamination of leukocyte-reduced apheresis platelets and leukocyte-reduced whole blood platelet concentrates. We do not have claims data describing the cost of the LVDS test. For CY 2022, we proposed to assign HCPCS code P9100 to APC 5732 (Level 2 Minor Procedures with a payment rate of approximately $33, which is the same APC assignment for HCPCS code P9100 as in CY 2021.

Comment: Two commenters requested we increase the payment rate for HCPCS code P9100 by moving the service from APC 5732 (Level 2 Minor Procedures) with payment rate of $32.98 to APC 5733 (Level 3 Minor Procedures) with a payment rate of $54.24. The commenters claim that the cost of the LVDS test is either $75 or $83, depending on which manufacturer's test is used, which is substantially higher than the approximately $30 cost of the rapid bacterial test for platelets. The commenters believe that the proposed payment rate of $32.98 for APC 5732 is too low to adequately compensate hospitals for the share of pathogen tests for platelets using the more expensive culture-based test, using LVDS. Commenters believed assigning HCPCS code P9100 to APC 5733 with a payment rate of $54.24 would better reflect the mixture of costs between culture-based platelet tests using LVDS and rapid bacterial tests.

Response: We agree with the commenters that the payment rate for HCPCS code P9100 should better reflect the resource cost of the anticipated mixture of rapid bacterial platelet tests and culture-based platelet tests, using LVDS, that will be used in CY 2022 to test for bacterial contamination in platelets. Therefore, we support the suggestion of the commenters to reassign HCPCS code P9100 to APC 5733 (Level 3 Minor Procedures) with a payment rate of $54.24.

After reviewing the public comments, we have decided to modify our proposal and reassign HCPCS code P9100 from APC 5732 (Level 2 Minor Procedures) to APC 5733 (Level 3 Minor Procedures) for CY 2022. The final CY 2022 payment rate for HCPCS code P9100 can be found in Addendum B to this CY 2022 OPPS/ASC final rule with comment period

which is available via the internet on the CMS website.

29. Pulmonary Rehabilitation (APC 5733)

For CY 2022, the AMA's CPT Editorial Panel created two new codes describing pulmonary rehabilitation services and requested that CMS delete HCPCS code G0424 (Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day). We proposed to assign CPT code 94625 (Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session)) and CPT code 94626 (Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; with continuous oximetry monitoring (per session)) to APC 5733 (Level 3 Minor Procedures) with a proposed payment rate of $57.12. We note that CPT codes 94625 and 94626 were listed as placeholder codes 946X1 and 946X2, respectively, in OPPS Addendum B of the CY 2022 OPPS/ASC proposed rule.

Comment: Several commenters disagreed with the proposed APC assignment and requested that CMS reassign CPT codes 94625 and 94626 to either APC 5721 (Level 1 Diagnostic Tests and Related Services) with a proposed payment rate of $143.21 or to APC 5771 (Cardiac Rehabilitation) with a proposed payment rate of $119.09. These commenters stated that these APCs better reflected the clinical similarity and costs associated with furnishing these services.

Response: CPT codes 94625 and 94626 do not describe diagnostic tests and so are not clinically similar to the other services in APC 5721. While clinically similar to cardiac rehabilitation services, predecessor HCPCS code G0424 has a geometric mean cost of $45.63 based on 198,132 single claims (out of 199,356 total claims), which is significantly lower than the geometric mean cost of $113.12 for the services in APC 5771. Based on our analysis, we believe that assignment of CPT codes 94625 and 94626 to APC 5733 is appropriate because their costs are consistent with the cost data of the predecessor code. We note that we review, on an annual basis, the APC assignments for all items and services paid under the OPPS. We will consider whether the current APC structure adequately reflects the clinical similarities and costs associated with pulmonary rehabilitation services in future rulemaking.

In summary, after consideration of the public comments, we are finalizing our proposal without modification to assign CPT codes 94625 and 94626 to APC 5733. The final CY 2022 OPPS payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

30. Sclerotherapy (APC 5054)

For CY 2022, we proposed to continue assignment of both CPT codes 36465 (Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (for example, great saphenous vein, accessory saphenous vein)) and CPT code 36466 (Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (for example, great saphenous vein, accessory saphenous vein), same leg) to APC 5054 (Level 4 Skin Procedures) with a proposed payment rate of $1,759.21.

Comment: One commenter disagreed with the proposed assignment of the procedures described by CPT codes 36465 and 36466 to APC 5054 and requested a reassignment to APC 5183 (Level 3 Vascular Procedures), which had a proposed payment rate of $2,937.76. The commenter stated that the per-procedure cost for the Varithena foam sclerosant used in the procedure is $1,054. The commenter stated that APC 5183 is more clinically appropriate and reflects the resources required to perform the procedure. Specifically, the commenter indicated that the procedures described by CPT codes 36465 and 36466 share similar clinical and resource characteristics to the following surgical procedures that are assigned to APC 5183:

- CPT code 36473 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated);
- CPT code 36475 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated); and
- CPT code 36478 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated).

The commenter also stated that the proposed geometric mean cost of $1,567.45 for 36465 would not be the lowest cost procedure if placed in APC 5183 and that the geometric mean costs of CPT code 36466 would be better aligned with APC 5183.

Response: Based on input from our clinical advisors, we believe that the procedures described by CPT codes 36465 and 36466 are clinically similar to the procedures assigned to APC 5054. We do not believe that the resources used for the procedures described by CPT codes 36465 and 36466 are comparable to the procedures described by CPT codes 36473, 36475, and 36478, which are assigned to APC 5183. We also note that the proposed geometric mean cost of $2,314.25 for CPT code 36466 is greater than the other codes with significant volume in APC 5183 and above the highest geometric mean cost of codes with significant volume in the next lower APC 5182 (Level 2 Vascular Procedures). Consequently, we believe that APC 5054 appropriately reflects the resources and clinical characteristics associated with the procedures described by CPT codes 36465 and 36466. We note that the geometric mean cost for APC 5054 is approximately $1,668.97, which exceeds the cost of the Varithena foam sclerosant ($1,054, as reported by the commenter) used in the procedure. We also note that the geometric mean costs for CPT codes 36465 and 36466 are well within the range of significant costs associated with APC 5054 ($1,402.75–$2,752.68).

Therefore, after consideration of the public comment received, we are finalizing our proposal without modification for assignment of the procedures described by CPT codes 36465 and 36466 to APC 5054. The final CY 2022 OPPS payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

31. Stromal Vascular Fraction (SVF) Therapy

For CY 2022, we proposed to continue assignment of CPT codes 0565T (Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular implant creation) and 0566T (Autologous

cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral) to status indicator ''E1'', indicating that these services are not paid by Medicare when submitted on outpatient claims.

Comment: One commenter supported this proposal and indicated that adipose-derived stromal vascular fraction (SVF) therapy for osteoarthritis is an unproven treatment. The commenter stated that FDA has issued several warnings about unproven cellular therapies and regenerative medicines since they offer no proven clinical benefits and may harm patients. The commenter further reported there is no indication for which SVF has been proven to be safe and effective in well-controlled clinical trials. To eliminate abuse by businesses seeking to profit from unproven treatments, the commenter suggested not paying for SVF therapy since unproven therapies create economic burdens on health systems and patients.

Response: We thank the commenter for their support.

In summary, after consideration of the public comment, we are finalizing our proposal without modification to continue assignment of CPT codes 0565T and 0566T to status indicator ''E1''. We refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

32. Synthetic Resorbable Skin Substitute

The CY 2014 OPPS/ASC final rule with comment period describes skin substitute products as ''. . . a category of products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers . . . [T]hese products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action that stimulate the host to regenerate lost tissue.'' (78 FR 74930 through 74931). The CY 2014 OPPS/ASC final rule with comment period also described skin substitutes as ''. . . a class of products that we treat as biologicals . . .'' and mentioned that prior to CY 2014, skin substitutes were separately paid in the OPPS as if they were biologicals according to the ASP methodology (78 FR 74930 through 74931).

The CY 2014 OPPS final rule with comment period did not specifically mention whether synthetic products could be considered to be skin substitute products in the same manner as biological products, because there were no synthetic products at that time that were identified as skin substitute products. Then in 2018, a manufacturer made a request that an entirely synthetic product that it claimed is used in the same manner as biological skin substitutes, receive a HCPCS code that would allow the product to be billed with graft skin substitute procedure codes, including CPT codes 15271 through 15278 and C5271 through C5278, starting in 2019. Initially, the synthetic product was not described as a graft skin substitute product. However, we now believe that both biological and synthetic products could be considered to be skin substitutes for Medicare payment purposes.

This view is supported by a paper referenced in a report we cited in the CY 2014 OPPS/ASC final rule with comment period titled ''Skin Substitutes for Treating Chronic Wounds Technology Assessment Report at ES–2'', which is available on the AHRQ website at: *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/skinsubs/HCPR0610_skinsubst-final.pdf.*

That paper, titled ''Regenerative medicine in dermatology: biomaterials, tissue engineering, stem cells, gene transfer and beyond'' by Dieckmann et al., states that skin substitutes should be divided into two broad categories: Biomaterial and cellular. The paper explains that ''. . . biomaterial skin substitutes do not contain cells (acellular) and are derived from natural or synthetic sources . . .'' The paper continues by describing biomaterial skin substitutes further: ''Synthetic sources include various degradable polymers such as polylactide and polyglycolide. Whether natural or synthetic, the biomaterial provides an extracellular matrix that allows for infiltration of surrounding cells.'' The paper by Dieckmann et al. indicates that skin substitute products may be synthetic products as well as biological products.

For CY 2021, we established a policy to include synthetic products in addition to biological products in our description of skin substitutes. Our new description defines skin substitutes as a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers. We also retained the additional description of skin substitute products from the CY 2014 OPPS final rule which states ''. . . that skin substitute products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue . . .'' (78 FR 74930 through 74931). Finally, our definition of skin substitutes does not include bandages or standard dressings and these items cannot be assigned to either the high cost or low cost skin substitute groups or be reported with either CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278. For CY 2022, we proposed to continue to report synthetic graft skin substitute products using HCPCS code C1849 in the same manner as in CY 2021.

Comment: As previously requested for CY 2021, several commenters requested that we establish product-specific HCPCS codes for synthetic graft skin substitute products and requested that we delete HCPCS code C1849 because the code is not product-specific. The primary reason commenters want product-specific codes for synthetic graft skin substitute is they feel that synthetic products should be assigned to either the high cost or low cost skin substitute group based on the cost of each individual product in a similar manner to biological skin substitute products. Commenters feel that because multiple synthetic graft skin substitute products can be assigned to HCPCS code C1849, there may be some synthetic products that should be in the low cost skin substitute group that will receive payment in the high cost skin substitute group if HCPCS code C1849 is assigned to the high cost group. Commenters also expressed concern about the opposite situation, in which high cost synthetic products would potentially be underpaid if HCPCS code C1849 is assigned to the low cost skin substitute group. Commenters believed the only resolution to these issues with HCPCS code C1849 is to delete the code and replace it with product-specific HCPCS codes for each graft synthetic product so there are not cases of synthetic products being either overpaid or underpaid.

Response: HCPCS code C1849 was established in response to the need to pay for graft skin substitute application services performed with synthetic graft skin substitute products in the OPPS in a manner comparable to how we pay for graft skin substitute application services performed with biological graft skin substitute products. As mentioned earlier in this section, when we established our policy in the CY 2014 OPPS/ASC final rule with comment period to package graft skin substitute

products into their associated application procedures (78 FR 74930 through 74931), we did not specifically mention whether synthetic products could be considered skin substitute products in the same manner as biological products. The reason for this was that there were no synthetic products at that time that were identified as skin substitute products.

We note that unless a graft skin substitute product has pass-through status, graft skin substitute products are not paid separately under unique HCPCS or CPT codes in OPPS. However, in CY 2018, a manufacturer requested that CMS develop methodologies to allow synthetic graft skin substitute products to receive payment in the outpatient hospital setting and in the physician office setting. After extensive review, we made the determination to assign the synthetic product in CY 2019 to HCPCS codes A6460 and A6461, which were newly created HCPCS codes to report synthetic, resorbable wound dressings. HCPCS codes A6460 and A6461 are packaged under the OPPS and cannot be assigned to either the high cost or low cost skin substitute group. This meant that graft skin substitute products could not be billed with CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278, even though synthetic graft skin substitute products and biological graft skin substitute products perform the same function and have similar efficacy. We quickly realized that using HCPCS codes A6460 and A6461 would not work to appropriately describe the application of synthetic graft products when used in similar manner to biological graft skin substitute products. Therefore, we needed to consider other approaches to this issue.

Because all skin substitutes, except those with pass-through status, are packaged under the OPPS, we explored solutions that would permit synthetic skin substitute products to be billed with either CPT codes 15271 through 15278 or HCPCS codes C5271 though C5278. We decided to create HCPCS code C1849 to describe any synthetic graft skin substitute product, and we revised the payment logic for the graft skin substitute application procedure codes to allow HCPCS code C1849 to be billed with those procedures. Multiple synthetic graft skin substitute products have now been identified as being described by HCPCS code C1849. We will average the pricing data from the various products to determine an amount for the products described by HCPCS code C1849 to compare against the MUC threshold. This comparison will determine if HCPCS code C1849 should be assigned to the high cost or low cost skin substitute category.

We appreciate the concerns expressed by commenters that one service code for synthetic products could lead to low cost synthetic graft products receiving excess payment if HCPCS code C1849 is assigned to the high cost group, or lead to high cost synthetic graft products being underpaid if HCPCS code C1849 is assigned to the low cost group. We will take these concerns into consideration in future rulemaking.

Comment: One commenter suggested that, if we do not establish product-specific HCPCS codes for each synthetic graft skin substitute product, we delete C1849 and establish two new HCPCS codes in its place. Specifically, the commenter recommended that one HCPCS code would be for high cost synthetic graft skin substitute products and the other HCPCS code would be for low cost synthetic graft skin substitute products. These two payment codes would ensure that all synthetic graft skin substitute products are assigned to the cost group that reflects whether the mean unit cost of any given synthetic graft skin substitute product is above or below the mean unit cost threshold for determining assignment to the high cost or low cost skin substitute group.

Response: We appreciate the suggestion from the commenter. We note that our policy is to allow all synthetic skin substitutes described by C1849 to bill the skin graft application CPT codes for high cost skin substitute products (CPT codes 15271 through 15278). We appreciate the commenters suggestion, which we will consider for future rulemaking.

Comment: One commenter provided suggestions on how we could revise our definition of synthetic graft skin substitute products to reduce the possibility that synthetic dressings or non-resorbable polymeric sheets could be considered synthetic skin substitute products and be reported using HCPCS code C1849.

Response: We thank the commenter for their suggestions. Currently, we do not believe that there is an issue with the definition of synthetic skin substitute products that we established for the CY 2021 OPPS/ASC final rule (85 FR 86064 through 86067). If during future rulemaking we find that synthetic graft products that do not function as skin substitutes are being reported using HCPCS code C1849, we may refer to the commenter's suggestions to help us revise our definition of synthetic graft skin substitute products.

33. Therapeutic Ultrafiltration (APC 5241)

As displayed in Addendum B to the CY 2022 OPPS/ASC proposed rule, we proposed to assign placeholder CPT code 0692T (Therapeutic Ultrafiltration) to SI ''E1'' to indicate that the code is not payable by Medicare when submitted on outpatient claims (any outpatient bill type) because the service associated with the code is either not covered by any Medicare outpatient benefit category, is statutorily excluded from Medicare payment, or is not reasonable and necessary. We note that CPT code 0692T was listed as placeholder code 057XT in OPPS Addendum B of the CY 2022 OPPS/ASC proposed rule.

Comment: Some commenters reported that the device associated with the CPT code 0692T describing therapeutic ultrafiltration received FDA approval by the U.S. Food and Drug Administration (FDA) in 2020 and requested separate payment for the code. They specifically requested assignment to APC 5242 (Level 2 Blood Product Exchange and Related Services) and SI ''S'' (Paid under OPPS; separate APC payment). They stated that CPT codes 36511 (Therapeutic apheresis; for white blood cells), and 36514 (Therapeutic apheresis; for plasma pheresis), which are assigned to APC 5242 and SI ''S,'' can be considered similar to therapeutic ultrafiltration in clinical and resource coherence.

Response: For CY 2022, OPPS payments are based on claims submitted between January 1, 2019, through December 31, 2019, and processed through June 30, 2020. Because CPT code 0692T is a new code that will be effective January 1, 2022, we have no claims data available for ratesetting. However, after further review of the service, we believe that CPT code 0692T shares similar clinical characteristics and resource costs as CPT code 36513 (Therapeutic apheresis; for platelets), which is currently assigned to APC 5241 (Level 1 Blood Product Exchange and Related Services). Therefore, we are assigning CPT code 0692T to APC 5241 and SI ''S'' for CY 2022. The final payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, the SI definitions can be found in Addendum D1 to this final rule with comment period. Both Addendum B and Addendum D1 are available via the internet on the CMS website.

We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS. As a result, we will reevaluate the APC

placement for CPT code 0692T for the next rulemaking cycle.

34. Transcatheter Implantation of Coronary Sinus Reduction Device

The Neovasc Reducer System is a novel device implanted into the coronary sinus vein using minimally invasive techniques. The Reducer is implanted by transvenous percutaneous approach from the right or left jugular vein into the coronary sinus. After positioning the balloon catheter at the implantation site, the Reducer is deployed by inflating the balloon catheter until apposition of the vessel wall is achieved. The balloon catheter is then deflated and removed from the coronary sinus, leaving the Reducer permanently inflated. After 6 to 8 weeks the hourglass shaped wire mesh is covered with endothelium and narrowing becomes effective by redistributing blood flow to ischemic areas of the heart.

In 2021, Neovasc received FDA approval for the Investigational Device Exemption (IDE) regarding the COSIRA–II Clinical Trial. COSIRA–II is a randomized, sham-controlled trial investigating the safety and effectiveness of the Reducer for patients suffering from refractory angina. Neovasc has been classified as a Category B device by FDA.

In addition, the AMA's Editorial Panel established a new code, specifically, CPT code 0645T (Transcatheter implantation of coronary sinus reduction device including vascular access and closure, right heart catheterization, venous angiography, coronary sinus angiography, imaging guidance, and supervision and interpretation, when performed), to describe the implantation of a coronary sinus reduction device that is associated with the Neovasc Reducer System. This code was effective July 1, 2021.

For CY 2022, we proposed to assign CPT code 0645T to SI ''E1'' to indicate that the code is not paid by Medicare when submitted on outpatient claims (any outpatient bill type).

Comment: One commenter, specifically, the manufacturer of the Neovasc Reducer System, requested assignment to either New Technology APC 1576 (New Technology—Level 39 ($15,001–$20,000) with the payment rate of $17,500.50, or New Technology APC 1577 (New Technology—Level 40 ($20,001–$25,000) with the payment rate of $22,500.50, in anticipation of its approval by Medicare for its Category B IDE study. The company stated there are no other surgical procedures that are similar in terms of resource costs and clinical homogeneity that would allow for the Neovasc Reducer System to be assigned to an appropriate clinical APC.

Response: Based on the information presented by the commenter, and our review of the IDE study, we do not believe that it is appropriate to assign a payable status indicator under the OPPS to CPT code 0645T prior to the approval of the Category B IDE study. In addition, the clinical study has not yet met CMS' standards for coverage, nor does it appear on the CMS Approved IDE List, which can be found at this CMS website: *https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html*. Because the Neovasc Reducer System has not been approved for Medicare coverage as a Category B IDE, we believe that we should continue to assign CPT code 0645T to status indicator ''E1''. If this technology later meets CMS's standards for coverage, we will assess the APC assignment for the code in a future quarterly update and/or rulemaking cycle.

Therefore, after consideration of the public comment, we are finalizing our proposal, without modification, to assign CPT code 0645T to SI ''E1''. We refer readers to Addendum D1 to this final rule with comment period for the complete list of the OPPS payment status indicators and their definitions for CY 2022. Addendum D1 is available via the internet on the CMS website.

35. Tympanostomy Using an Automated Tube Delivery System (APC 5163)

For CY 2022, we proposed to continue to assign CPT code 0583T to APC 5163 (Level 3 ENT Procedures) with a proposed payment rate of $1,387.72.

Comment: A few commenters disagreed with our proposed APC assignment. These commenters stated that CPT code 0583T should be reassigned to APC 5164 (Level 4 ENT Procedures) or APC 1523 (New Technology—Level 23 ($2,501–$3,000)) with proposed payment rates of $2,806.94 and $2,750.50, respectively. Commenters stated that CPT code 0583T is clinically similar to CPT code 69421 (Myringotomy including aspiration and/or eustachian tube inflation requiring general anesthesia), which is assigned to APC 5164. Commenters further stated that APC 5164 also includes many other middle ear procedures that involve an incision, revision, repair, and removal of tubes.

Response: We disagree with commenters on the clinical similarity between CPT code 0583T and the other services in APC 5164. For the reasons discussed in the CY 2021 OPPS final rule with comment period (85 FR 85983), based on our review of the procedure and input from our medical advisors, we continue to believe that the surgical procedure described by CPT code 0583T is most similar, in terms of clinical homogeneity and resource cost, to CPT code 69436 (Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia), which is assigned to APC 5163. Both procedures (as described by CPT codes 0583T and 69436) require ventilating tubes that require anesthesia.

In summary, after consideration of the public comments, we are finalizing our proposal without modification to continue assignment of CPT code 0583T to APC 5163. The final CY 2022 OPPS payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

36. Urology and Related Services (APCs 5371 Through 5378)

For CY 2016, we established the APC reorganization and developed a urology specific series of APCs 5371–5377. Since that time, we have maintained that structure and added an additional level 8, APC 5378 (Level 8 Urology and Related Services). Based on our analysis of the CY 2019 claims available for ratesetting, we proposed to continue the 8 level structure of Urology APCs in the CY 2022 OPPS. We received comments on the CY 2022 OPPS/ASC proposed rule suggesting we revise the APC assignments for the services assigned to the Urology & Related Services APCs. A commenter specifically noted that a reorganization for APCs 5375 through 5376 would be appropriate, but added that there were other adjustments across services within the Urology APCs that could improve the structure of these APCs.

We received several comments on APC reassignments. Below are the comments and our responses.

a. High-Intensity Focused Ultrasound of the Prostate (HIFU) Procedure (APC 5375)

In 2017, CMS received a new technology application for the prostate HIFU procedure and established a new code, specifically, HCPCS code C9747 (Ablation of prostate, transrectal, high intensity focused ultrasound (hifu), including imaging guidance). Based on the estimated cost provided in the new technology application, we assigned the new code to APC 5376 (Level 6 Urology and Related Services) with a payment rate of $7,452.66 effective July 1, 2017.

We announced the SI and APC assignment in the July 2017 OPPS quarterly update CR (Transmittal 3783, Change Request 10122, dated May 26, 2017).

For the CY 2018 update, we maintained the assignment of HCPCS code C9747 to APC 5376 with a payment rate of $7,596.26. We note that the payment rates for the CY 2018 OPPS update were based on claims submitted between January 1, 2016 through December 30, 2016, that were processed on or before June 30, 2017. Since HCPCS code C9747 was established on July 1, 2017, we had no claims data for the procedure for use in ratesetting for CY 2018.

However, for the CY 2019 update, based on the latest claims data for the final rule, we revised the APC assignment for HCPCS code C9747 from APC 5376 to APC 5375 with a payment rate of $4,020.54. We note that the payment rates for CY 2019 were based on claims submitted between January 1, 2017 through December 30, 2017, that were processed on or before June 30, 2018. Our claims data showed a geometric mean cost of approximately $5,000 for HCPCS code C9747 based on 64 single claims (out of 64 total claims), which was significantly lower than the geometric mean cost of about $7,717 for APC 5376. We believed that the geometric mean cost for HCPCS code C9747 was more comparable to the geometric mean cost of approximately $4,055 for APC 5375. Consequently, we reassigned the code from APC 5376 to APC 5375 (Level 5 Urology and Related Services) for CY 2019 and C9747 remained in APC 5375 for CY 2020.

For the CY 2021 update, we replaced HCPCS code C9747 with CPT code 55880 (Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (hifu), including ultrasound guidance) on January 1, 2019. We maintained the assignment of HCPCS code C9747 to APC 5375 with a payment rate of $4,413.90. We note that the payment rates for the CY 2021 OPPS update were based on claims submitted between January 1, 2019 through December 30, 2019, that were processed on or before June 30, 2020. Our claims data showed a geometric mean cost of approximately $5,744,43 for HCPCS code C9747 (CPT code 55880) based on 279 single claims (out of 284 total claims), which was assigned to APC 5375 with a geometric mean cost of about $4,299.81.

For CY 2022, we proposed to continue to assign HCPCS code C9747 to APC 5375 with a proposed payment rate $4,527.23.

Comment: Several commenters requested CPT code 55880 be reassigned to APC 5376 from APC 5375. The commenters argued that the average cost of the HIFU procedure is closer to the APC 5376 proposed payment rate of $8,468.32. Several commenters recommended we assign this procedure to APC 5376 because they believe the service is clinically similar and comparable in terms of resources to cryoablation of the prostate, which is described by CPT code 55873 (Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring) and assigned to APC 5376 (Level 6 Urology and Related Services), with a proposed payment rate of $8,468.32. They also stated that the new CPT code 55880 descriptor treats malignant prostate tissue, which requires additional resources relative to its predecessor code descriptor that treated BPH. Some commenters stated that the CY 2019 OPPS reassignment of HCPCS code C9747 to APC 5375 from APC 5376 was due to inaccurate and incomplete claims that did not include the substantial cost of the disposable device required for the procedure and stated that HIFU is a device-intensive procedure. They alleged the underpayment for HIFU discourages hospitals from providing this procedure for Medicare patients because the APC 5375 payment rate does not cover the hospital facility cost for this procedure. They alleged that maintaining the assignment in APC 5375 will deter HOPD facilities from offering the HIFU treatment to Medicare beneficiaries because the payment is insufficient to cover the cost of the procedure. Several commenters argued that the current HIFU payment is a health equity issue because Americans in a lower socio-economic class will have less access to high-quality healthcare. Furthermore, the commenters stated that prostate cancer affects more men of color whose rate of death is almost twice that of non-Hispanic white men.

Response: We review, on an annual basis, the APC assignments for all services and items (including devices) paid under the OPPS based on our analysis of the latest claims data. For CY 2021, based on predecessor HCPCS code C9747, our claims data supported maintaining CPT code 55880 in APC 5375. For CY 2022, based on our analysis of the claims for this CY 2022 OPPS/ASC final rule with comment period, our data shows a geometric mean cost of approximately $5,708 for HCPCS code C9747 based on 279 single claims, which is more comparable to the geometric mean cost of about $4,299 for APC 5375, rather than the geometric mean cost of approximately $8,042 for APC 5376. Although we are not applying the CY 2020 claims data for the CY 2022 ratesetting due to the PHE, we noted that the geometric mean cost associated with HCPCS code C9747 is about $6,654, which is between the geometric means of APC 5375 and APC 5376. Our clinical advisors also acknowledge the clinical and resource similarity between CPT code 55880 and CPT code 55873, both of which are treatment options for prostate cancer. We performed several APC modeling studies on the impact of reassigning a set of codes to better balance the procedures within APC 5375 and 5376, and we found that the reassignment of these codes would impact the payment level of both APC 5375 and 5376.

In summary, after careful consideration of the public comments, and after our analysis of the claims data for this final rule with comment period, we are maintaining the APC assignment for CPT code 55880 in APC 5375, but will consider its reassignment in future rulemaking. The final CY 2022 payment rate for CPT code 55880 can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

b. Rezūm Procedure—Water Vapor Thermotherapy (APC 5373)

In 2018, CMS established a new code, specifically, HCPCS code C9748 (Transurethral destruction of prostate tissue; by radiofrequency water vapor (steam) thermal therapy). Based on its estimated cost, we assigned the new code to APC 5373 (Level 3 Urology and Related Services) with a payment rate of $1,695.68 effective January 1, 2018. We announced the SI and APC assignment in the January 2018 OPPS quarterly update CR (Transmittal 3941, Change Request 10417, dated December 22, 2017).

For the CY 2019 update, we replaced HCPCS code C9748 with CPT 53854 (Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy) on January 1, 2019. We maintained the assignment of CPT 53854 (HCPCS code C9748) to APC 5373 with a payment rate of $1,695.57. We note that the payment rates for the CY 2018 OPPS update were based on claims submitted between January 1, 2017 through December 30, 2017, that were processed on or before June 30, 2018. Since HCPCS code C9748

was established on January 1, 2018, we had no claims data for the procedure for use in ratesetting for CY 2019.

For the CY 2020 update, we maintained the assignment of HCPCS code 53854 to APC 5373 with a payment rate of $1,771.35. We note that the payment rates for the CY 2020 OPPS update were based on claims submitted between January 1, 2018 through December 30, 2018, that were processed on or before June 30, 2019. Our claims data showed a geometric mean cost of approximately $1,899.18 for HCPCS code C9748 based on 191 single claims (out of 192 total claims), which was assigned to APC 5373 with a geometric mean of about $1,733.35.

For the CY 2021 update, we maintained the assignment of HCPCS code 53854 to APC 5373 with a payment rate of $1,792.99. We note that the payment rates for the CY 2020 OPPS update were based on claims submitted between January 1, 2019, through December 30, 2019, that were processed on or before June 30, 2020. Our claims data showed a geometric mean cost of approximately $2,414.69 for HCPCS code 53854 based on 751 single claims (out of 752 total claims), which was assigned to APC 5373 with a geometric mean cost of about $1,746.64.

For CY 2022, we proposed to continue to assign HCPCS code 53854 to APC 5373 with a proposed payment rate $1,839.83.

Comment: A commenter requested the reassignment of CPT code 53854 to APC 5374 (Level 4 Urology and Related Services) from APC 5373 (Level 3 Urology and Related Services). The commenter stated the geometric mean costs associated with CPT Code 53854 are significantly higher than either all significant or almost all significant other procedures in APC 5373. The commenter further stated that based on the CY 2019 claims data, CPT code 53854 yields a geometric mean cost of about $2,410 with 751 single frequency claims and suggested the geometric mean cost of CPT code 53854 is much closer to the geometric mean cost of APC 5374, which is approximately $2,996. The commenter cited the year over year increase in geometric cost of 18 percent or $423 from 2019 to 2020. In addition, the commenter stated CPT 53854 is a transurethral procedure for the treatment of benign prostatic hyperplasia (BPH) and is more clinically similar to the two transurethral BPH procedure codes CPT 53850 (Transurethral destruction of prostate tissue; by microwave thermotherapy) and CPT 53852 (Transurethral destruction of prostate tissue; by radiofrequency thermotherapy) assigned to APC 5374.

Response: We appreciate the commenter's input on this subject. Based on our evaluation of the latest claims data for this final rule with comment period, we noted the geometric mean cost associated with CPT code 53854 (HCPCS C9748) increased from $1,899.18 (from the CY 2018 claims data) to $2,412.55 (from the CY 2019 claims data), which represented an approximately 27 percent increase year-over-year. Based on our review, our medical advisors agreed with the commenter that CPT code 53854 is similar to CPT code 53850 and CPT code 53852 in terms of clinical characteristics and resource. We noted that CPT codes 53850 and 53852 represent treatment options for BPH which are assigned to APC 5374 (Level 4 Urology and Related Services) while there are no BPH treatment procedures assigned to APC 5373 with the exception of CPT code 53854.

In summary, after consideration of the public comments, we are finalizing our proposal with modification and reassigning CPT code 53854 to APC 5374 from APC 5373 for CY 2022. The final CY 2022 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

37. VisONE Synchronized Diaphragmatic Stimulation (SDS) System

For CY 2022, the CPT Editorial Panel created CPT codes 0674T through 0685T, which are listed in Table 29, to describe the VisONE® Synchronized Diaphragmatic Stimulation™ (SDS®) System. For CY 2022, we proposed to assign these codes to OPPS SI ''E1'', indicating that these services are not paid by Medicare when submitted on outpatient claims. We note these codes were listed as placeholder codes 050XT through 055XT in OPPS Addendum B of the CY 2022 OPPS/ASC proposed rule.

BILLING CODE 4120–01–P

TABLE 29: VISONE® SDS SYSTEM CPT CODES

CPT Codes	Placeholder Codes	Long Descriptor
0674T	050XT	Laparoscopic insertion of new or replacement of permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including an implantable pulse generator and diaphragmatic lead(s)
0675T	051XT	Laparoscopic insertion of new or replacement of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; first lead
0676T	060XT	Laparoscopic insertion of new or replacement of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; each additional lead (List separately in addition to code for primary procedure)
0677T	061XT	Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; first repositioned lead
0678T	062XT	Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; each additional repositioned lead (List separately in addition to code for primary procedure)
0679T	063XT	Laparoscopic removal of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function
0680T	052XT	Insertion or replacement of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing lead(s)
0681T	064XT	Relocation of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing dual leads
0682T	065XT	Removal of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function
0683T	053XT	Programming device evaluation (in-person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function

CPT Codes	Placeholder Codes	Long Descriptor
0684T	054XT	Peri-procedural device evaluation (in-person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review, and report by a physician or other qualified health care professional, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function
0685T	055XT	Interrogation device evaluation (in-person) with analysis, review and report by a physician or other qualified health care professional, including connection, recording and disconnection per patient encounter, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function

Comment: A commenter reported that the device associated with these codes has been approved for Breakthrough Device Designation by the FDA. The commenter added that they are currently in the process of applying for Medicare national coverage for the clinical trial as a Category B IDE study. The commenter requested that we crosswalk the new codes to the SIs and APC assignments of comparable procedures involving other stimulation technologies so that appropriate hospital outpatient payment may be made in the event the Category B IDE study is approved for Medicare coverage. The commenter listed the comparable codes with the SI and APCs assignments. See Table 30 for SI and APC assignments requested by commenter.

Table 30: VISONE® SDS SYSTEM SI and APC Assignment Requested by Commenter

HCPCS code	Requested SI	Requested APC
0674T	J1	5465
0675T	J1	5463
0676T	N	N/A
0677T	J1	5462
0678T	N	N/A
0679T	J1	5462
0680T	J1	5464
0681T	J1	5461
0682T	J1	5461
0683T	S	5742
0684T	N	N/A
0685T	S	5741

BILLING CODE 4120–01–C

Response: The clinical trial associated with CPT codes 0674T through 0685T does not appear on the CMS Approved IDE List, which can be found at this CMS website: *https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html*. While we recognize the commenter's assertion that is was accepted for FDA's Breakthrough Device Designation and that it intends to apply for Medicare coverage as a Category B IDE clinical trial, since the clinical trial associated with these codes has not been approved for Medicare coverage, we believe we should continue to assign CPT codes 0674T through 0685T to SI ''E1'' for CY 2022. If Medicare approves the clinical trial as a Category B IDE study, we will reassess the SI and APC assignments for the codes.

In summary, after consideration of the public comments, we are finalizing our proposal without modification. Specifically, we are finalizing our continued assignment of CPT code=0674T through 0685T to OPPS SI ''E1.''

IV. OPPS Payment for Devices

A. Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

The intent of transitional device pass-through payment, as implemented at § 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). Under section 1833(t)(6)(B)(iii) of the Act, the period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years. Prior to CY 2017, our regulation at § 419.66(g) provided that this pass-through payment eligibility period began on the date CMS established a particular transitional pass-through category of devices, and we based the pass-through status expiration date for a device category on the date on which pass-through payment was effective for the category. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79654), in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category.

In addition, prior to CY 2017, our policy was to propose and finalize the

dates for expiration of pass-through status for device categories as part of the OPPS annual update. This means that device pass-through status would expire at the end of a calendar year when at least 2 years of pass-through payments had been made, regardless of the quarter in which the device was approved. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79655), we changed our policy to allow for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices. We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the current device pass-through payment policy.

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. Currently, there are 11 device categories eligible for pass-through payment. These devices are listed in Table 31. Below, we detail the expiration dates of pass-through payment status for each of the 11 devices currently receiving device pass-through payment.

The pass-through payment status of the device category for HCPCS code C1823 is scheduled to expire on December 31, 2021. Typically, we would propose to package the costs of the device described by C1823 into the costs related to the procedure with which the device is reported in the hospital claims data for CY 2022. The data for the CY 2022 OPPS proposed rule ratesetting for the procedure reported with C1823 would have been set using CY 2020 outpatient claims data processed through December 31, 2020, however, as described in section X.E. of the CY 2022 OPPS/ASC proposed rule (86 FR 42188), due to the effects of the COVID–19 PHE, we proposed to use CY 2019 claims data instead of CY 2020 claims data in establishing the CY 2022 OPPS rates and to use cost report data from the same set of cost reports originally used in final rule 2021 OPPS ratesetting. Therefore, we proposed to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to provide separate payment for C1823 for four quarters of CY 2022 to end on December 31, 2022. This would allow for CY 2021 claims data to inform CY 2023 rate setting for the procedure reported with C1823. This is the only device whose costs would typically be packaged into the related procedure in CY 2022 using CY 2020 claims data for ratesetting and is the only device to which this proposed policy would apply. A full discussion of this finalized policy is included in section X.F. of this CY 2022 OPPS/ASC final rule.

The pass-through payment status of the device category for HCPCS code C1823 will end on December 31, 2021. The pass-through payment status of the device categories for HCPCS codes C1824, C1982, C1839, C1734, and C2596 is set to expire on December 31, 2022. The pass-through payment status of the device category for HCPCS code C1748 is set to expire on June 30, 2023. The pass-through payment status of the device category for HCPCS codes C1052, C1062, and C1825 is set to expire on December 31, 2023 and the pass-through payment status of the device category for HCPCS code C1761 is set to expire on June 30, 2024. Table 31 shows the expiration dates of transitional pass-through payments for these devices.

BILLING CODE 4120–01–P

TABLE 31: EXPIRATION OF TRANSITIONAL PASS-THROUGH PAYMENTS FOR CERTAIN DEVICES

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2021
C1824	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023
C1052	Hemostatic agent, gastrointestinal, topical	1/1/2021	12/31/2023
C1062	Intravertebral body fracture augmentation with implant (e.g., metal, polymer)	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s)	1/1/2021	12/31/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024

BILLING CODE 4120–01–C

2. New Device Pass-Through Applications for CY 2022

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations are most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629). We note that, as discussed in section IV.A.2. of the CY 2022 OPPS/ASC proposed rule (86 FR 42085), we created an alternative pathway in the CY 2020 OPPS/ASC final rule that granted fast-track device pass-through payment under the OPPS for devices approved under the FDA Breakthrough Device Program for OPPS device pass-through payment applications received on or after January 1, 2020. We refer readers to section IV.A.4. of the CY 2022 OPPS/ASC proposed rule for a complete discussion of this pathway.

As specified in regulations at § 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA marketing authorization (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing

authorization is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;

•The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and

• The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should be established. The device to be included in the new category must—

• Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;

• Have an average cost that is not ''insignificant'' relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)); and

• Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly subregulatory process, but the applications will be subject to notice and- comment- rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

In the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation (84 FR 61295) and receive FDA marketing authorization. Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that are part of the Breakthrough Devices Program, have received FDA marketing authorization, and meet the other criteria in the regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle. This process promotes timely pass-through payment status for innovative devices, while also recognizing that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html,* in the ''Downloads'' section. In addition, CMS is amenable to meeting with applicants or potential applicants to discuss research trial design in advance of any device pass-through application or to discuss application criteria, including the substantial clinical improvement criterion.

Comment: One commenter recommended that, for devices with FDA Breakthrough Device designation, CMS remove the requirement that the device prove they are not described by an existing transitional pass-through category. The commenter asserted that FDA Breakthrough Device designation implies that a device is a first of kind in addressing the condition for which it is indicated.

Response: We appreciate the commenter's input but note that we did not propose to eliminate the device category requirement in the CY 2022 OPPS/ASC proposed rule. Moreover, section 1833(t)(6)(B)(ii) requires the Secretary to establish categories of medical devices in a manner such that no medical device is described by more than one category and to promptly establish a new category of medical devices for any new medical devices for which none of the categories in effect or previously in effect is appropriate.

Comment: One commenter asked that CMS provide additional guidance to medical technology innovators to help clarify requirements for demonstrating ''substantial clinical improvement'' for purposes of transitional pass-through payment eligibility. The commenter stated that greater clarity should be provided in particular with regard to the evidence types and study designs that may be considered in evaluating substantial clinical improvement, including methods beyond randomized clinical trials (RCTs) that would produce evidence sufficient to demonstrate substantial clinical

improvement in a shorter period of time and at reduced cost.

Response: We appreciate the commenter's input, but note that this comment is outside the scope of this rulemaking. We refer the commenter to the Device Pass-through application located on the CMS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf*) for further information regarding what evidence is considered in evaluating substantial clinical improvement of devices.

Comment: One commenter offered their general support for our proposal to approve all eight applications for device pass-through status included in the CY 2022 OPPS/ASC proposed rule. The commenter added that CMS needs to ensure that pass-through payment amounts adequately cover the cost of the device to ensure that Medicare beneficiaries have access to innovative services and reduce facilities' economic burdens. The commenter also believed CMS should refrain from factoring a procedure off-set amount into the calculation of payment for these transitional pass though approved services.

Response: We appreciate the general support for our proposals to approve the applications discussed in the CY 2022 OPPS/ASC proposed rule and the recommendations provided by the commenter. Our determinations on each application are described in detail in the next section. As we have in prior years, CMS continues to evaluate the application of the device offset amount on a case by case basis to ensure the appropriate payment is made for a device on pass-through status. In cases where a device on pass-through status replaces previously existing technologies, we continue to believe it is appropriate to apply the device offset amount.

b. Applications Received for Device Pass-Through Payment for CY 2022

We received eight complete applications by the March 1, 2021 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in the CY 2022 OPPS/ASC proposed rule. We received three of the applications in the third quarter of 2020, two of the applications in the fourth quarter of 2020, and three of the applications in the first quarter of 2021. One of the applications was approved for device pass-through payment during the quarterly review process: the Shockwave C^2 Coronary Intravascular Lithotripsy (IVL) catheter, which received fast-track approval under the alternative pathway effective July 1, 2021. As previously stated, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle. Therefore, the Shockwave C^2 Coronary Intravascular Lithotripsy (IVL) catheter is discussed in section IV.2.b.1. of this final rule with comment period.

Applications received for the later deadlines for the remaining 2021 quarters (June 1, September 1, and December 1), if any, will be discussed in the CY 2023 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed in light of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.*

Discussions of the applications we received by the March 1, 2021 deadline are included below.

1. Alternative Pathway Device Pass-through Applications

We received two device pass-through applications by the March 2021 quarterly application deadline for devices that have received Breakthrough Device designation from FDA and FDA marketing authorization, and therefore are eligible to apply under the alternative pathway. As stated above in section IV.2.a of the CY2022 OPPS/ASC proposed rule, under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but need to meet the other requirements for pass-through payment status in our regulation at § 419.66.

(1) RECELL® System

AVITA Medical submitted an application for a new device category for transitional pass-through payment status for the RECELL® System (RECELL®) for CY 2022. According to the applicant, RECELL® is used to process autologous donor tissue into a cell suspension autograft that is then immediately applied to the surgically prepared acute thermal burn wound.

The applicant stated RECELL® is a stand-alone, single-use, battery-powered device used to process and apply an autologous skin cell suspension. According to the applicant, RECELL® is a Class III medical device indicated for the treatment of acute partial-thickness and full-thickness/mixed depth thermal burn wounds and is not categorized as a skin substitute.

According to the applicant, the autograft procedure utilizing the RECELL® system involves harvesting a small graft from the patient's healthy skin and placing it into the RECELL® System for immediate processing into an autologous skin cell suspension. The applicant asserts that a significantly smaller autograft harvest is needed for procedures involving RECELL® when compared to procedures involving a split-thickness skin graft (STSG) without RECELL®; where typical STSG expansion ranges from 2:1 to 6:1, RECELL® may expand skin by up to 80:1. The applicant adds the entire procedure takes place in the operating room, including surgically preparing the acute burn wound, harvesting the autograft, processing the skin cell suspension through a disaggregation process, and applying the cell suspension autograft to the wound with no culturing in a laboratory.

The applicant described the RECELL® procedure in 27 steps: (1) The autograft site is identified; (2) the patient is anesthetized and prepared; (3) the nurse opens and transfers the sterile RECELL® System to the operative field; (4) a self-test is performed; (5) the nurse prepares and dispenses the enzyme into the incubation well; (6) the buffer solution is drawn and dispensed into the buffering and rinsing well; (7) the RECELL® processing unit is activated to heat the enzyme; (8) a thin epidermal autograft is harvested; (9) the harvested skin graft is placed in the enzyme; (10) the donor graft incubates for 15–20 minutes; (11) the sample is placed dermal side down in the mechanical scraping tray; (12) a scalpel is used to scrape the edges of the skin sample; (13) once ready, the donor skin is rinsed in the buffer solution; (14) the skin is returned to the mechanical scraping tray; (15) buffer is applied to the skin sample; (16) the skin sample is held in place with forceps; (17) the surgeon scrapes the epidermal cells; (18) the buffer syringe is used to rinse the disaggregated skin cells; (19) the surgeon draws up the autologous skin cell suspension from the tray into a syringe; (20) the suspension is then dispensed through the cell strainer to filter the suspension; (21) the filtered autologous skin cell suspension is drawn into a new 10 ml syringe; (22) the cell suspension autograft is prepared; (23) the burn wound is debrided; (24) the primary dressing (non-adherent,

non-absorbent, small pore) is fixed or held only at the lower aspect of the burn wound; (25) the cell suspension autograft is applied by either spraying or dripping over the prepared wound bed; (26) after application, the primary dressing is immediately secured over the wound bed; and (27) absorbent and protective dressings are then applied as needed.

The applicant states the autologous skin cell suspension prepared using the RECELL® System contains keratinocytes, fibroblasts and melanocytes. According to the applicant, keratinocytes are the primary cells of the epidermis that are responsible for healing; fibroblasts enable the creation of new extracellular matrix proteins; and melanocytes produce melanin to allow restoration of normal pigmentation. The applicant asserts the unique delivery system allows for broad and even distribution of the cell suspension autograft directly onto a prepared wound surface or in combination with a meshed skin graft.

According to the applicant, there is one commercially available product (Epicel) that is also used to create an autograft from the patient's skin that is then applied to treat acute thermal burns. The applicant's claims regarding the differences between the two products are summarized in the following Table 32:

BILLING CODE 4120–01–P

TABLE 32: DIFFERENCES BETWEEN RECELL® AND EPICEL ACCORDING TO APPLICANT

RECELL®	Epicel
Indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients	Indicated for use in adult and pediatric patients who have deep dermal or full thickness burns
Used to treat acute thermal burns up to 50% total body surface area (TBSA)	Used to treat acute thermal burns with TBSA greater than or equal to 30%
Class III device approved under PMA process. Includes electromagnetic warnings to include that it should not be used in presence of flammable anesthetic.[24] Contraindicated for treatment of infected or necrotic tissue, in those hypersensitive to trypsin or sodium lactate solution.[25]	Approved under a Humanitarian Device Exception (HDE). HDE devices are exempt from the effectiveness requirements for PMAs.[26] Includes a black box warning noting a serious risk of squamous cell carcinoma.[27] Contraindicated in those with history of hypersensitivity following exposure to vancomycin, amikacin, or amphotericin or those with sensitivities to bovine or murine materials.[28]
Requires a single operative session to treat the patient.	Surgical procedures separated by a period of two or more weeks are required for harvesting and placement of cultured tissue sheets. Multiple operative sessions may also be required for cultured tissue sheet placements.
Cell suspension autograft prepared in the operating room and immediately applied	Harvested autograft cultured in an off-site laboratory, taking approximately 17 days to

RECELL®	Epicel
	culture for application at a later date[29]
No blood samples needed	Blood samples must be taken and archived on the date of the procedure per FDA protocol

BILLING CODE 4120–01–C

With respect to the newness criterion at § 419.66(b)(1), RECELL® is part of the FDA Breakthrough Devices Program. The applicant stated that RECELL® received PMA on September 20, 2018. The applicant added that RECELL® is a Class III medical device indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older. We received the application for a new device category for transitional pass-through payment status for RECELL® on August 7, 2020, which is within 3 years of the date of the initial FDA marketing authorization. We invited public comment on whether the RECELL® meets the newness criterion.

Comment: The applicant reiterated that RECELL® received FDA PMA on September 20, 2018.

Response: We appreciate the commenter's input. Because we received the RECELL® pass-through application on August 7, 2020, which is within 3 years of September 20, 2018, the date of FDA premarketing approval, we agree that the RECELL® meets the newness criterion. With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, RECELL® is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion. The applicant also claimed that RECELL® meets the device eligibility requirements of § 419.66(b)(4) because it is not equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. However, given the applicant's description of RECELL® as a device that processes tissue into an autograft, we stated that it appears that the RECELL® system may not be surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion. We noted that we believed the product of the RECELL® system, the suspension, may be applied on a wound, but we were not certain that this suspension qualifies as a device. We invited public comments on whether RECELL® meets the eligibility criteria at § 419.66(b).

Comment: In response to our concern regarding whether the suspension, that is applied in or on a wound or other skin lesion is the device for purposes of the requirement in § 419.66(b) one commenter stated that FDA approved all components of the RECELL® as a device, and that in order to treat a patient, all components of the RECELL® device are required to treat the patient. Multiple commenters stated the process of harvesting, creating and applying the suspension as one continuous process would not be possible without the device hardware; the hardware and suspension are tightly integrated and there is no treatment without the suspension. Another commenter added that the buffer solution is a component of the RECELL® device, which allows the expansion of the donor skin and provides a suspension mechanism for the skin cells to be applied directly on the patient's burn wound.

Response: We thank the commenters for their input. We have taken this information into consideration in our final determination of whether the device meets the criteria in § 419.66(b)(3) and § 419.66(b)(4), discussed below.

Comment: The applicant asserted that RECELL® is an integral part of the service, which cannot be performed without all device components including the suspension, is used for a single patient only, comes in contact with human tissue and is applied on a wound, and therefore, the applicant believes the RECELL® device meets the criteria in § 419.66(b)(3).

In response to our concern that the device is not applied in or on a wound or other skin lesion, the applicant stated that the RECELL® device is intended to harvest the cells from the patient's own donor skin to create a skin cell suspension which is then applied directly on the debrided and excised burn wound using a syringe fitted with a spray nozzle. According to the applicant, the RES Regenerative Epidermal Suspension (''Suspension'') contains autologous skin cells and buffer solution, a RECELL® device component, which is directly applied in or on a wound. The applicant added that the buffer is a pH neutral solution (sodium lactate) in liquid form that is used to carry, expand, and deliver the harvested skin cells in the RES Suspension for direct application to the burn wound. According to the applicant, RECELL® could not accomplish its intended use as described in its FDA label without the buffer, which is a necessary component of the device. The applicant and another commenter also contended that the Suspension qualifies as a device under FDA's definition, and cited provisions of the Federal Food, Drug, and Cosmetic Act and FDA guidance that they believed supported this position,

Response: We appreciate the additional information from the applicant and commenters. The applicant and commenters indicated that the RECELL® device consists of several components, one of which is the buffer, which is combined with harvested skin cells to create the suspension that is then applied to a wound. Because the buffer, a component of the device, is part of the

[24] Instructions for use—RECELL® Autologous Cell Harvesting Device. Food and Drug Administration. *https://www.fda.gov/media/116382/download.*

[25] Ibid.

[26] Humanitarian Device Exemption (HDE) Program—Guidance for Industry and FDA Staff. U.S. Department of Health and Human Services. Food and Drug Administration. Issued September 6, 2019. Accessed on March 30, 2021 and available at: *https://www.fda.gov/media/74307/download.*

[27] Manufacturer Important Drug Warning: Serious Risk with Use of Epicel (cultured epidermal autografts): Squamous Cell Carcinoma (SCC). June 2014. Food and Drug Administration. Accessed on March 30, 2021 and available at: *https://www.fda.gov/media/102746/download.*

[28] Directions for Use—Epicel (cultured epidermal autograpfts). Food and Drug Administration. *https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/epicel-cultured-epidermal-autografts.*

[29] Epicel Surgical Guidelines. Epicel website. Accessed on March 30, 2021 and available at: *https://www.epicel.com/pdfs/Epicel%20Surgical Guide%202018%20DIGITAL.pdf.*

suspension that is applied in or on a wound, RECELL® meets the eligibility criterion specified at § 419.66(b)(3)). We did not receive any comments in regard to § 419.66(b)(4), whether the device is equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and whether the device is a supply or material furnished incident to a service. Because the applicant asserted that the RECELL® device met the eligibility requirements at § 419.66(b)(4) and we agree, we conclude that the RECELL® device meets this eligibility criterion.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We stated in the CY 2022 OPPS/ASC proposed rule that we have not yet identified an existing pass-through payment category that describes RECELL®. We invited public comment on whether RECELL® meets the device category criterion.

Comment: The applicant asserted the RECELL® meets the first criterion for establishing a new device category at § 419.66(c)(1) because there are no existing categories established for device TPT that describe the RECELL® device.

Response: We agree there is no existing pass-through payment category that appropriately describes the RECELL® because no current category appropriately describes a device that creates a suspension from an autograft of the patient's skin that is then applied to treat acute thermal burns. Based on this information, we have determined that the RECELL® meets the first eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization. As previously discussed in section IV.2.a above, we finalized the alternative pathway for devices that are granted a Breakthrough Device designation and receive FDA marketing authorization in the CY 2020 OPPS/ASC final rule (84 FR 61295). The RECELL® System has a Breakthrough Device designation and marketing authorization from FDA, and therefore, is not evaluated for substantial clinical improvement. We note that the applicant applied for new technology add-on payment under the alternative pathway for Breakthrough devices, as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45150 through 45151). While we have determined that the RECELL® device meets the newness criterion for OPPS device pass-through eligibility, in the FY 2022 IPPS/LTCH PPS final rule, we found that the RECELL® device was not within the newness period for FY 2022 for eligibility for new technology add-on payments and was therefore ineligible to receive these payments (86 FR 45151).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that RECELL® would be reported with the HCPCS codes listed in the following Table 33:

TABLE 33: HCPCS CODES REPORTED WITH RECELL®

HCPCS Code	Short Descriptor	SI	APC
Epidermal Autograft Procedures			
15110	Epidrm autogrft trnk/arm/leg	T	5054
15111	Epidrm autogrft t/a/l add-on	N	
15115	Epidrm a-grft face/nck/hf/g	T	5054
15116	Epidrm a-grft f/n/hf/g addl	N	
Split-Thickness Skin Graft Procedures			
15100	Skin splt grft trnk/arm/leg	T	5054
15101	Skin splt grft t/a/l add-on	N	
15120	Skn splt a-grft fac/nck/hf/g	T	5055
15121	Skn splt a-grft f/n/hf/g add	N	
Surgical Preparation Procedures			
15002	Wound prep trk/arm/leg	T	5054
15003	Wound prep addl 100 cm	N	
15004	Wound prep f/n/hf/g	T	5053
15005	Wnd prep f/n/hf/g addl cm	N	

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. In the CY 2022 OPPS/ASC proposed rule, we stated that for our calculations, we used APC 5054—Level 4 Skin Procedures, which had a CY 2020 payment rate of $1,622.74 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 15110 had a device offset amount of $13.47 at the time the application was received. According to the applicant, the cost of the RECELL® is $7,500.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $7,500 for RECELL® is 462 percent of the applicable APC payment amount for the service related to the category of devices of $1,622.74 ((7,500/1,622.74) × 100 = 462.2 percent). Therefore, we stated in the CY 2022 OPPS/ASC proposed rule that we believe RECELL® meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $7,500 for RECELL® is 55,679 percent of the cost of the device-related portion of the APC payment amount for the related service of $13.47 (($7,500/$13.47) × 100 = 55,679.3 percent). Therefore, we stated in the CY 2022 OPPS/ASC proposed rule that we believe RECELL® meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $7,500 for RECELL® and the portion of the APC payment amount for the device of $13.47 is 461 percent of the APC payment amount for the related service of $1,622.74 ((($7,500 − $13.47)/$1,622.74) × 100 = 461.4 percent). Therefore, we stated in the CY 2022 OPPS/ASC proposed rule that we believe RECELL® meets the third cost significance requirement.

We invited public comment on whether the RECELL® meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: One commenter asserted that RECELL® expands the donor skin by up to 80x compared to 2–4x for most autografts, the current standard of care. The commenter stated this is an important treatment option in light of the ongoing COVID–19 pandemic and its drain on the availability of inpatient bed space. The commenter respectfully requested that CMS approve the RECELL® pass-through payment application to make RECELL® available in the outpatient setting. A second commenter offered their general support for approval of RECELL® based on what they believe to be substantial improvements compared to current burn treatments. A third commenter urged CMS to finalize pass-through status for RECELL® so that they could offer the treatment to patients on an outpatient basis.

Response: We thank the commenters for their support and we note that, as explained further below, we are approving RECELL® for device pass-through status beginning in CY 2022.

Comment: The applicant stated that the cost of RECELL® is not insignificant and exceeds 25 percent of the applicable APC amount for the relevant procedures that would be reported with RECELL®. The applicant further stated that the cost of the RECELL® device also exceeds the device-related portion of the applicable APC amount by more than 25 percent for the relevant procedures that would be reported with RECELL®.

Response: After consideration of the public comments we received and our review of the device pass-through application, we have determined that RECELL® meets the requirements for device pass-through payment status described at § 419.66. As stated previously, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but must meet the other criteria for device pass-through status, and we believe RECELL® meets those other criteria.

Therefore, effective beginning January 1, 2022, we are finalizing approval for device pass-through payment status for RECELL® under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization.

(2) Shockwave C² Coronary Intravascular Lithotripsy (IVL) Catheter

Shockwave Medical submitted an application for a new device category for transitional pass-through payment status for the Shockwave C² Coronary Intravascular Lithotripsy (IVL) catheter (Coronary IVL Catheter) for CY 2022. The applicant asserts the Coronary IVL Catheter is a proprietary lithotripsy device delivered through the coronary arterial system of the heart to the site of an otherwise difficult to treat calcified stenosis, including calcified stenosis that is anticipated to exhibit resistance to full balloon dilation or subsequent uniform coronary stent expansion. According to the applicant, energizing the lithotripsy device generates intermittent sound waves within the target treatment site, disrupting calcium within the lesion and allowing subsequent dilation of a coronary artery stenosis using low balloon pressure. According to the applicant, the Coronary IVL System is comprised of the following components:

(1) IVL Generator—a portable, rechargeable power source that is capital equipment and reusable.

(2) IVL Connect Cable—a reusable cable used to connect the IVL Generator to the IVL Catheter.

(3) Coronary IVL Catheter—a sterile, single-use catheter that delivers intravascular lithotripsy within the target coronary lesion.

According to the applicant, during a percutaneous coronary intervention (PCI) procedure, the physician determines that a lesion has severe calcification. The applicant states the Coronary IVL Catheter is introduced into the lesion where lithotripsy is delivered to crack the calcification to facilitate the optimal dilatation of the vessel and placement of a coronary stent. The applicant adds that the Coronary IVL Catheter is removed, and the physician then implants a coronary stent to treat the lesion.

The applicant asserts that the Coronary IVL Catheter is different from other devices used during PCI procedures as it delivers localized lithotripsy to crack the calcified lesion prior to the placement of a coronary stent. According to the applicant there are other devices that may be utilized to remove calcium within the vessel (that is, atherectomy), however, these devices utilize some form of cutting or laser to remove or ablate the calcium and can

only address the calcium nearest to the vessel lumen. According to the applicant, the Coronary IVL Catheter addresses the calcium within the lumen as well as within the vessel walls.

According to the applicant, the Coronary IVL Catheter is used to treat a subset of patients identified for a PCI procedure to treat their coronary artery disease where approximately 15 percent of lesions in patients being eligible for a PCI procedure have severe calcification. The applicant adds the Coronary IVL Catheter is utilized during PCI procedures and does not replace any devices currently utilized to complete the procedure (for example, guidewires, angioplasty balloons, stent(s), vascular closure, etc.) that are packaged into the APC payment rate. According to the applicant, based on the FDA labeling for the Coronary IVL catheter, it is utilized prior to the placement of a coronary stent.

With respect to the newness criterion at § 419.66(b)(1), the Coronary IVL Catheter received FDA PMA for the Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C2 Coronary Intravascular Lithotripsy (IVL) Catheter on February 12, 2021 and is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting. The Coronary IVL Catheter received FDA Breakthrough Device designation on August 19, 2019, and is indicated for lithotripsy-enabled, low-pressure dilatation of calcified, stenotic de novo coronary arteries prior to stenting. We received the application for a new device category for transitional pass-through payment status for the Coronary IVL Catheter on February 26, 2021, which is within 3 years of the date of the initial FDA marketing authorization. We invited public comment on whether the Coronary IVL Catheter meets the newness criterion.

Comment: One commenter stated that the Coronary IVL Catheter meets the newness criteria.

Response: We thank the commenter for the information.

Comment: In their comment the applicant concurred with CMS' conclusion that Coronary IVL Catheter meets the transitional pass-through criteria and supported CMS finalizing the transitional-pass through status for three years.

Response: Because we received the Coronary IVL Catheter pass-through application on February 26, 2021, which is within 3 years of February 12, 2021, the date of FDA premarketing approval for the device, we agree that the Coronary IVL Catheter meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Coronary IVL Catheter is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted in a patient until the procedure is completed. The applicant also claimed that the Coronary IVL Catheter meets the device eligibility requirements of § 419.66(b)(4) because it is not equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. In the CY 2022 OPPS/ASC proposed rule, we invited public comments on whether the Coronary IVL Catheter meets the eligibility criteria at § 419.66(b).

Comment: One commenter stated that the regulation at § 419.66(b)(3) is clear that pass-through is not appropriate for ''equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1).'' [30] The commenter stated we acknowledged in the CY 2022 OPPS/ASC proposed rule that the Shockwave System Generator, which is the ''power source'' for the Shockwave System, is ''capital equipment'' [31] with the list price referenced for the Coronary IVL System and not just the Coronary IVL Catheter.[32] Next the commenter stated that the proposed rule does not consider if the Generator, an excluded piece of capital equipment, is the key component of the Coronary IVL System, and contended that CMS did not consider whether the Generator, an excluded piece of capital equipment is a ''key therapeutic component'' of the Shockwave System, and as such, that the Shockwave System as a whole should not be eligible for device pass-through status.

Response: As we stated in the CY 2022 OPPS/ASC proposed rule (86 FR 42089), Shockwave Medical submitted an application for a new device category for transitional pass-through payment status for the Coronary IVL Catheter, and not for the remainder of the Coronary IVL System, which includes the IVL Cable and Generator. Given that the IVL Cable and Generator are not single-use devices, they are not eligible for device pass-through status. The only part of this device that is eligible for device pass-through status is the Coronary IVL Catheter—a sterile, single-use catheter.

In terms of the commenter's contention that we have not evaluated which portion of the device is the key therapeutic component, we emphasize that the Coronary IVL Catheter is the device for which the applicant submitted an application for device pass-through status. We also note that we consider which portion of a combination product is the key therapeutic or diagnostic component solely for purposes of determining whether implantable biological products should be evaluated as drugs or devices for pass-through payment purposes (74 FR 60476). We do not determine which portion of a combination product is the key therapeutic or diagnostic component for purposes of analyzing a device's eligibility for pass-through status. Nonetheless, if we were to consider the Shockwave Coronary IVL System as a whole, we would conclude that the Coronary IVL Catheter is the key therapeutic component as it is the component in the Shockwave System that is introduced into the lesion where lithotripsy is delivered to crack the calcification to facilitate the optimal dilatation of the vessel and placement of a coronary stent.

Comment: The applicant concurred with CMS' conclusion that the Coronary IVL Catheter meets the transitional pass-through criteria, including the criteria at § 419.66(b), and supported CMS finalizing the transitional-pass through status for the Coronary IVL Catheter for 3 years.

Response: Based on the information we have received and our review of the application, we agree with the applicant that the Coronary IVL Catheter is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, and therefore meets the requirements in § 419.66(b)(3). We also agree with the commenter that the Coronary IVL Catheter meets the device eligibility requirements of § 419.66(b)(4) because it is not equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. Based on this assessment we have determined that the Coronary IVL Catheter meets the eligibility criteria at § 419.66(b)(3) and (4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS

[30] 42 CFR 419.66(b)(4); Medicare Provider Reimbursement Manual, Ch. 1, section 104.1.

[31] 86 FR 42089.

[32] 86 FR 45153.

determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant identified five established categories which they believe are not appropriate representatives of the Coronary IVL Catheter: (1) C1714 and C1724, which include devices that use mechanical cutting tools; (2) C1725, which includes balloon angioplasty; (3) C1885, which uses laser, beams of light to break up vessel obstructions; and (4) C2623, which includes a drug coated balloon. We stated in the CY 2022 OPPS/ASC proposed rule that we had not identified an existing pass-through device category that describes Coronary IVL Catheter and we invited public comment on this issue.

Comment: In its comment, the applicant concurred with CMS' conclusion that Coronary IVL Catheter meets the transitional pass-through device category eligibility criteria at § 419.66(c)(1) and supported CMS finalizing transitional pass-through status for three years.

Response: We agree there is no existing pass-through device category that appropriately describes the Coronary IVL Catheter because no current category describes a balloon catheter that generates sonic pressure waves using lithotripsy that can break up calcification in arterial walls. Based on this information, we have determined that the Coronary IVL Catheter meets the eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization. As previously discussed in section IV.2.a above, we finalized the alternative pathway for devices that are granted a Breakthrough Device designation and receive FDA marketing authorization in the CY 2020 OPPS/ASC final rule (84 FR 61295). The Coronary IVL Catheter has a Breakthrough Device designation and marketing authorization from FDA, and therefore, is not evaluated for substantial clinical improvement. We note that the applicant applied for the new technology add-on payment under the alternative pathway for Breakthrough devices as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45151 through 45153). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45153), CMS approved the Coronary IVL Catheter for new technology add-on payments.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the Coronary IVL Catheter meeting the cost significance requirements. The applicant stated that the Coronary IVL Catheter would be reported with the HCPCS codes listed in the following Table 34:

BILLING CODE 4120–01–P

TABLE 34: HCPCS CODES REPORTED WITH CORONARY IVL CATHETER

HCPCS Code	Short Descriptor	SI	APC
92928	Prq card stent w/angio 1 vsl	J1	5193
92929	Prq card stent w/angio addl	N	
92933	Prq card stent/ath/angio	J1	5194
92934	Prq card stent/ath/angio	N	
92941	Prq card revasc mi 1 vsl	C	
92943	Prq card revasc chronic 1vsl	J1	5193
92944	Prq card revasc chronic addl	N	
C9600	Perc drug-el cor stent sing	J1	5193
C9601	Perc drug-el cor stent bran	N	
C9602	Perc d-e cor stent ather s	J1	5194
C9603	Perc d-e cor stent ather br	N	
C9606	Perc d-e cor revasc w ami s	C	
C9607	Perc d-e cor revasc chro sin	J1	5194
C9608	Perc d-e cor revasc chro add	N	

BILLING CODE 4120–01–C

To meet the cost criterion for establishing a device category, a device must pass all three cost criteria for at least one APC. For our calculations for the CY 2022 OPPS/ASC proposed rule, we used APC 5193—Level 3 Endovascular Procedures, which had a CY 2021 payment rate of $10,042.94 at the time the application was received.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost for the Coronary IVL Catheter of $5,640 is 56 percent of the applicable APC payment amount for the service related to the category of devices of $10,042.94 (($5,640/10,042.94) × 100 = 56 percent). Therefore, we stated in the CY 2022 OPPS/ASC proposed rule that we believe the Coronary IVL Catheter meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 92928 had a device offset amount of $3,607.42 at the time the application was received. The estimated average reasonable cost for the Coronary IVL Catheter of $5,640 is 156 percent of the cost of the device-related portion of the APC payment amount for the related service of $3,607.42 (($5,640/$3,607.42) × 100 = 156 percent). Therefore, we stated in the CY 2022 OPPS/ASC proposed rule that we believe that the Coronary IVL Catheter meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $5,640 for the Coronary IVL Catheter and the portion of the APC payment amount for the device of $3,607.42 is 20 percent of the APC payment amount for the related service of $10,042.94 (($5,640 − $3,607.42)/$10,042.94) × 100= 20 percent). Therefore, we stated in the CY 2022 OPPS/ASC proposed rule that we believe that the Coronary IVL Catheter meets the third cost significance requirement.

We invited public comment on whether the Coronary IVL Catheter meets the device pass-through payment criteria discussed in this section,

including the cost criterion for device pass-through payment status.

Comment: One commenter asserted that CMS' review of the Shockwave System (Coronary IVL) was based on an incorrect CPT/APC pairing and an assessment of charges, not actual costs.

The commenter stated that CMS' analysis is contrary to its own regulation because it did not reference ''the applicable APC.'' [33] According to the commenter, if APC 5194 (Level 4 Endovascular Procedures) is used to assess the Shockwave System, and not APC 5193 (Level 3 Endovascular Procedures), it is clear that the Shockwave System would not meet any of the three cost criteria. The commenter makes a number of arguments about why it believes APC 5194 is ''the applicable APC,'' including that that the applicant referenced 92933 (Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch) which the commenter explains maps to APC 5194, not APC 5193.[34] According to the commenter, the applicant is clearly targeting this APC, as the applicant references a targeted population of patients with calcified lesions of approximately 15 percent of patients; [35] this population maps to I25.84 (Coronary atherosclerosis due to calcified coronary lesion) for which a matching percentage of patients links to 92933 (and APC 5194), not 92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch) (and APC 5193).[36] The commenter further asserted that in its development of the Shockwave System, the applicant references coronary orbital atherectomy (OA), which, in fact, breaks up and removes calcium, as occurs in atherectomy.[37] According to the commenter, the applicant's public comments clearly present the Shockwave System as a replacement to atherectomy.[38] The commenter stated that the proposed rule states that the pass-through criteria can be satisfied if ''any'' APC meets the criteria but refers to the regulation, which states the pass-through cost criteria can be met if ''the applicable'' APC is used. The commenter contended that it is clear the applicable APC for the Shockwave System is 5194 and not 5193. The commenter added that some stakeholders are under a misconception that, if the Shockwave System is granted pass-through status based on an analysis of the cost criterion using a pairing of 92928 and APC 5153, additional pass-through payments will nevertheless be available when the Shockwave System is billed under APC 5194. The commenter asked CMS to ensure, if the agency confirms its quarterly pass-through determination for the Shockwave System, that appropriate safeguards are in place so that inappropriate payments are not made in connection with APC 5194.

The commenter next asserted that the Shockwave System cost significance test is based on list prices and not costs, is inadequately supported, and is inconsistent with available cost data. According to the commenter, the device cost used in assessing the cost criteria requirement reflects a list price and is contrary to publicly available information on Shockwave System pricing. The commenter stated that there are substantially more C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch) claims (*i.e.,* 90,889) with drug-eluting stents than 92928 (*i.e.,* 6,357) with bare metal stents, where the device-related portion is higher. The commenter asserted that CMS did not provide any information in the CY 2022 OPPS/ASC proposed rule about why 92928 was used instead of C9600. The commenter explained that it is not clear to them why CMS chose 92928 instead of C9600 to perform the cost significance calculations for the cost criterion.

The commenter then asserted that CMS, without providing factual support, stated that the average reasonable cost for Coronary IVL is $5,640. According to the commenter, in the IPPS/LTCH final rule (86 FR 44774, 45153) CMS used a value of $5,640 for the Shockwave System, but did not reference the IPPS/LTCH final rule in the CY 2022 OPPS/ASC proposed rule. The commenter went on to explain that CMS based this figure on a cost for the Shockwave System of $4,700 per device × 1.2 devices required per case, and stated that CMS finalized this cost for the System ''as a whole'' without supporting this calculation except using preliminary information from the applicant. The commenter asserted that, under the Administrative Procedures Act, 5 U.S.C. 553(b), an agency is required, in order to provide stakeholders with reasonable notice and opportunity to comment, to provide the factual basis that supports its proposal; the commenter added that CMS' failure to provide any support for its proposal is precisely the kind of defect in process that courts have repeatedly cautioned against.

According to the commenter, in a published article, citing a Shockwave earnings call, the Shockwave national list price was stated to be $4,700.[39] The commenter asserted that a list price is a charge and not a reflection of actual cost and does not address any discounts, rebates, free goods contingent on a purchase, or other price concessions. The commenter noted that blinded market research revealed prices to some purchasers as low as $4,200 and possibly lower.

Additionally, the commenter noted that in the proposed rule the applicant used a multiplier of 1.2 devices required per case to calculate the $5,640 used in assessing whether the device meets the cost criterion. According to the commenter, such a multiplier is not cited in the proposed rule and was not, therefore, framed appropriately for comment as part of this rulemaking. The commenter added three concerns related to the multiplier: (1) Use of a multiplier magnifies the invalid impact of incorrectly included ''equipment'' (the Generator) and a reusable item (the Cable) because the Generator and Cable would not be used in more than one case; (2) neither the CY 2022 OPPS proposed rule nor the FY 2022 IPPS/LTCH final rule included data or support for the assertion that 1.2 devices are required per case; and (3) use of a multiplier is not appropriate where, as here, the pass-through regulation requires a ''reasonable'' estimate of costs and more than one device would be used in less than twenty percent of all cases. The commenter contended that CMS should use medians, rather than

[33] 42 CFR 419.66(d)(1).

[34] See CY 2022 OPPS Notice of Proposed Rulemaking Addendum B.

[35] 86 FR 42018, 42089 (August 4, 2021).

[36] 2019 Medicare Outpatient Claims data (showing 17.21 percent of 92933 is associated with I25.84).

[37] The Shockwave System's PMA was based in part on results from DISRUPT CAD III, which was designed to enroll the same population, using the same definitions and endpoints as in ORBIT II, which was the pivotal trial that paved the way for orbital atherectomy's approval in 2013. See Shelley Wood, MD, ''FDA Approves Shockwave Intravascular Lithotripsy for Calcified Coronaries'', available at *https://www.tctmd.com/news/fda-approves-shockwave-intravascular-lithotripsy-calcified-coronaries* (Feb. 16, 2021).

[38] See Shockwave Investor Presentation (August 2021), available at *https://ir.shockwavemedical.com/static-files/84cb0382-3ad6-435e-a6de-1a132160ff68* (stating that the Shockwave System is a ''Solution'' to ''Atherectomy'' and its ''Serious Complications'').

[39] Shelley Wood, tctMD, ''FDA Approves Shockwave Intravascular Lithotripsy for Calcified Coronaries'', available at *https://www.tctmd.com/news/fda-approves-shockwave-intravascular-lithotripsy-calcified-coronaries* (February 16, 2021).

averages, because of what the commenter believed was the inaccurate nature of averages in circumstances like these.[40]

Response: We appreciate the additional information provided by the commenter. We disagree with the commenter's assertion that the proposed rule references the incorrect HCPCS/APC pairing. Question D.7. of the device pass-through application states: Using Healthcare Common Procedure Coding System (HCPCS) Level I and/or Level II code(s), list all of the specific procedure(s) and/or services with which the nominated device is used. The applicant for the Coronary IVL Catheter provided a complete list of HCPCS codes with which their device can be billed. CMS evaluated the complete list of HCPCS codes to ensure each code represented a procedure with which the Coronary IVL Catheter could be used. Consistent with our evaluation of every other device pass-through application, we identify the applicable APC with which to evaluate the cost of the device against the cost significance tests at § 419.66(d). There are numerous APCs to which procedures with which the Coronary IVL Catheter can be performed are assigned. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Furthermore, we disagree with the commenter's assertion that CMS should limit pass-through payments to one APC (5193) versus another (5194). The applicant identified HCPCS codes which CMS agrees align appropriately to both APC 5193 and 5194. Consistent with CMS' policy, we are not limited in applying pass-through payments to only the HCPCS/APC combination that was used in the cost significance test, but rather the entire list of procedures which appropriately represent the technology.

We disagree with the commenter's assertions that the CY 2022 OPPS/ASC proposed rule uses an assessment of charges, as opposed to cost, and failed to give commenters an opportunity to comment. As we stated in the proposed rule, according to the applicant the Coronary IVL System is comprised of the following components: (1) IVL Generator—a portable, rechargeable power source that is capital equipment and reusable; (2) IVL Connect Cable—a reusable cable used to connect the IVL Generator to the IVL Catheter; (3) Coronary IVL Catheter—a sterile, single-use catheter that delivers intravascular lithotripsy within the target coronary lesion. Given that parts one and two are not single-use devices, they are not under consideration for device pass-through status. The only part of this device which is under consideration for device pass-through payments is the Coronary IVL Catheter—a sterile, single-use catheter. According to the applicant, the expected average sales price of each Shockwave C2 Coronary IVL single-use catheter is $4,700. We acknowledge that in the CY 2022 OPPS/ASC proposed rule, we did not state that, per the applicant, the average number of catheters required per case is 1.2 based on the applicant's clinical trial experience; the applicant therefore calculated an expected cost to hospitals on a per-case basis for the Coronary IVL Catheter of $5,640. Based on our analysis, which includes a review by CMS clinical professionals, we agree with the applicant that the average number of catheters required per case is 1.2 and therefore, that a multiplier of 1.2 is appropriate in this situation. We appreciate the commenter identifying this information. We note that regardless of the value used, $4,700 (for one Coronary IVL Catheter per case) or $5,640 (for 1.2 Coronary IVL Catheters per case), the Coronary IVL Catheter meets the cost significance tests at § 419.66(d). Finally, we are clarifying that although the FY 2022 IPPS/LTCH PPS final rule referred to the Shockwave C2 Intravascular Lithotripsy (IVL) System when discussing whether the device met the cost criterion for new technology add-on payments, we considered the cost only of the Coronary IVL Catheter in that determination.

Comment: This same commenter asserts that the proposed rule failed to provide stakeholders with a reasonable opportunity to comment on issues central to the pass-through determination. The commenter asserted that the quarterly, sub-regulatory determination made for pass-through status for the Coronary IVL Catheter is invalid following the Supreme Court's decision in *Azar* v. *Allina Health Services,* 139 S. Ct. 1804 (2019). Based on these assertions, the commenter stated that the Coronary IVL Catheter should not be approved for pass-through status and the quarterly determination should be rescinded. The commenter stated that our process of approving applications for device pass-through status on a quarterly basis predates the Supreme Court's decision in *Allina* and should ''appropriately conform to the rulemaking obligations set forth in *Allina*''.[41] The commenter concludes that the Shockwave System pass-through determination was invalid and in excess of CMS' authority and it should, therefore, be rescinded.

Response: We disagree with the commenter's assertion that the quarterly determination process is invalid, and that the quarterly, sub-regulatory determination to grant pass-through status for the Coronary IVL Catheter is invalid following *Allina.* We note that in the CY 2016 OPPS/ASC final rule (80 FR 70417–70418) CMS finalized through notice and comment rulemaking its proposal to revise the application process for device pass-through payments. Specifically, CMS stated that starting in CY 2016 all device pass-through payment applications submitted through the quarterly process would be subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle. Furthermore, under the finalized policy, CMS stated that all applications that are approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, and any information provided by the applicant would be available for consideration during the public comment process for the proposed rule. CMS stated that this process would allow those applications that meet all criteria to receive timely pass-through payment status, while also allowing for a transparent public review process for all applications as part of the next available rulemaking. Finally, we note that the quarterly approval process does not establish or change a substantive legal standard governing the scope of benefits or the payment for services, but only applies substantive legal standards adopted through notice and comment rulemaking to determine whether a particular device should qualify for pass-through status.

Comment: In their public comment, the applicant stated that there are two issues associated with CMS' evaluation and implementation of transitional device pass-through payment status for the Coronary IVL Catheter that they wanted to bring to CMS' attention. In CMS Transmittal 10825, dated June 11, 2021, CMS limited HCPCS code C1761 to being reported with two procedures that describe placement of a coronary stent (HCPCS codes 92928 and C9600). The applicant noted that CMS most recently published Transmittal 10997, dated September 16, 2021, which added four additional HCPCS codes—92933,

[40] 42 CFR 419.66(d).

[41] CMS Memorandum, Impact of Allina on Medicare Payment Rules, at 1 (Oct. 31, 2019). See also section 1871(a)(2) of the Act.

92943, C9602, and C9607—that can also be billed in conjunction with HCPCS code C1761 and be eligible for transitional pass-through effective July 1, 2021. The applicant noted that CMS included the device offset associated with these codes when calculating the incremental transitional pass-through payment when HCPCS code C1761 is billed. The applicant believes CMS applied the device offset for HCPCS codes 92933, 92943, C9602, and C9607 as an oversight, and requested that CMS remove the device offset for these codes when calculating the incremental transitional pass-through payment when billed in conjunction with C1761 because, similar to the determination for HCPCS codes 92928 and C9600, no device offset should be implemented as IVL costs are completely additive to the procedure and the devices represented by the device offset in each procedure are still required.

Response: We disagree with the applicant's request to remove the device offset for HCPCS codes 92933, 92943, C9602 and C9607 when calculating the incremental transitional pass-through payment when billed in conjunction with HCPCS code C1761. In the above-identified procedures, the Coronary IVL Catheter is used in lieu of atherectomy to achieve a therapeutic outcome. Therefore, we believe a device offset as identified in Transmittal 10997 dated September 16, 2021 is warranted when HCPCS code C1761 is used in conjunction with these particular procedures.

Comment: The applicant stated that while they agree that Coronary IVL Catheter meets all three cost criteria based on CMS' methodology, they are concerned that the methodology CMS utilizes is not the most appropriate for procedures that require the use of multiple devices. The applicant contends that CMS utilizes the entire device-related portion (DRP) as reported for the applicable procedure instead of evaluating the cost of the new technology relative to the specific devices that it is replacing. The applicant asserted that CMS has removed the device offset for other technologies that have received transitional pass-through payment where new technologies are completely additive to the procedure. The applicant stated that CMS does not utilize a similar methodology when evaluating the three cost criteria. The applicant asserted that this may create an artificially high bar that would make new technology that would otherwise qualify for pass-through status ineligible, which the applicant believes is the case for the Eluvia™ system. The applicant requested that CMS update its methodology for current and future transitional pass-through applications where multiple devices are utilized.

Response: We thank the applicant for their input in regard to the calculation of the cost significance criterion, which we will take into consideration for future rulemaking. For a more detailed discussion of this issue as it relates to the Eluvia™ system, please see section IV(a)(2)(b)(3) of this final rule with comment period.

After consideration of the public comments we received and our review of the device pass-through application, we have determined that Coronary IVL Catheter meets the requirements for device pass-through payment status described at § 419.66. As stated previously, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but must meet the other criteria for device pass-through status, which we believe the Coronary IVL Catheter does.

As specified above, the Coronary IVL Catheter pass-through application was preliminarily approved for transitional pass-through payment under the alternative pathway effective July 1, 2021. We note that in the CY 2022 OPPS/ASC proposed rule we invited public comments on whether the Coronary IVL Catheter should continue to receive transitional pass-through payment under the alternative pathway for devices that are FDA market authorized and that have an FDA Breakthrough Device designation.

We are finalizing our proposal to continue in 2022 device pass-through payment status for the Coronary IVL Catheter under the alternative pathway for devices that have an FDA Breakthrough Device designation and have FDA marketing authorization.

2. Traditional Device Pass-Through Applications

(1) AngelMed Guardian® System

Angel Medical Systems submitted an application for a new device category for transitional pass-through payment status for the AngelMed Guardian® System (the Guardian®) for CY 2022. The applicant asserted that the Guardian® is a proactive diagnostic technology that monitors a patient's heart's electrical activity for changes that may indicate an Acute Coronary Syndrome (ACS) event (that is, STEMI, NSTEMI, or unstable angina) related to blockage of a coronary artery which prevents the heart muscle from receiving sufficient oxygen. The Guardian® is a device implanted in the upper left chest and connects to an active fixation intracardiac lead attached to the apex of the right ventricle. The applicant asserts the Guardian® consists of an implantable medical device (IMD) which is composed of the header with an antenna for communication and the can with circuitry, radio, vibratory motor, and battery. According to the applicant, the Guardian® system also includes an external device that communicates with the IMD and provides redundant patient notification using auditory and visual alarms. Lastly, the applicant states the Guardian® system includes a physician programmer, a capital device, used to program the IMD and download cardiac data captured by the IMD.

According to the applicant, the Guardian® system relies upon the gold standard of changes to the ST-segment of a patient's heartbeat to diagnose a heart attack. According to the applicant, the Guardian® system uses an intracardiac lead to sense cardiac data and proprietary machine learning algorithms to assess acute changes to the ST-segment on a continuous, real-time basis. The applicant asserts these changes are compared to a patient's normal baseline reference that is computed over the prior twenty-four hours of monitored heart activity. According to the applicant, if the Guardian® detects a statistically abnormal acute change relative to this baseline, it notifies the patient to the potential ACS event by providing an alarm: The implanted device will vibrate, and the external device will flash and beep. According to the applicant, patients are instructed to seek urgent medical assistance when the system activates, even in the absence of ACS symptoms.

According to the applicant, the Guardian® system implantation will typically be an outpatient procedure and, following 10–14 days, is programmed in the physician office. The applicant asserts the patient undergoes training on the Guardian® and has follow-up visits every six months to review the device data. The applicant states that the emergency alarm is intended to be used as an adjunct to symptoms; in the absence of an emergency alarm patients are instructed not to ignore symptoms of an ACS event. The applicant asserts that while current technologies detect and provide therapy for cardiac medical conditions related to abnormal heart rate and rhythm, the AngelMed Guardian® system is the only FDA-

approved technology for providing detection and patient notification of ACS events so that patients more reliably and urgently seek medical care.

With respect to the newness criterion at § 419.66(b)(1), the AngelMed Guardian® system first received FDA 510(k) clearance on April 9, 2018 under PMA number P150009. The manufacturers received a Category B Investigational Device Exemption (IDE) as of January 27, 2020 for the use of the device in their continued access study, AngelMed for Early Recognition and Treatment of STEMI (ALERTS). According to the applicant, the device is anticipated for US market availability in quarter three of 2021. We received the application for a new device category for transitional pass-through payment status for the Guardian® system on February 28, 2021, which is within 3 years of the date of the initial FDA marketing authorization. We solicited public comment in the CY 2022 OPPS/ASC proposed rule on whether the Guardian® system meets the newness criterion.

Comment: The applicant reasserted that the Guardian® meets the newness criterion at § 419.66(b)(1) as the application was submitted within 3 years of FDA approval.

Response: We appreciate the commenter's input and agree that because we received the application for the Guardian® on February 28, 2021, which was within 3 years of the FDA premarketing approval on April 9, 2018, the Guardian® meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Guardian® is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted temporarily. The applicant also claimed that the Guardian® meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We invited public comments in the CY 2022 OPPS/ASC proposed rule on whether the Guardian® meets the eligibility criteria at § 419.66(b).

Comment: The applicant stated the Guardian® meets the eligibility criteria at § 419.66(b)(3) and 419.66(b)(4) as the Guardian® is used for one patient only, comes in contact with human tissue, and is surgically inserted.

Response: Based on the information we have received and our review of the application, we agree with the applicant that the device is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted. We also agree with the commenter that the Guardian® meets the device eligibility requirements of § 419.66(b)(4) because it is not equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. Based on this assessment we have determined that the Guardian® meets the eligibility criterion at § 419.66(b)(3) and (4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We stated in the CY 2022 OPPS/ASC proposed rule that we have not yet identified an existing pass-through payment category that describes the Guardian®. We invited public comment on whether the Guardian® meets the device category criterion.

Comment: The applicant asserted the Guardian® meets the first criterion for establishing a new device category, at § 419.66(c)(1), as no existing categories or categories previously in effect appropriately describe the technology.

Response: We agree there is no existing pass-through payment category that appropriately describes the Guardian® because no current or previously in effect category describes a device that provides detection of ACS events and notification to a patient. Based on this information, we have determined that the Guardian® meets the eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization.

The applicant stated that the Guardian® represents a substantial clinical improvement over existing technologies. With respect to this criterion, the applicant asserted that the Guardian® 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 is currently possible and this earlier diagnosis results in better outcomes.[42] In support of this claim the applicant submitted two published articles, the first by Gibson et al. and the second by Holmes et al.[43] [44]

The first study is a randomized control trial with 907 subjects who were implanted with the Guardian® system and randomized 1:1 to either active or deactivated alarms.[45] According to the authors, all subjects received education regarding the importance of minimizing symptom-to-door time in the presence of chest pain or ischemic equivalents, regardless of alarm status. The authors state that patients were not blinded to their randomization status. After randomization patients returned for follow-up visits at 1, 3, 6, and every six months thereafter. In all patients, the Guardian® system captured electrogram data up to 24 hours before and 8 hours after a triggered alarm for later review. According to the authors, the primary safety endpoint was the absence of system-related complications that required a system revision or invasive intervention to resolve in at least 90 percent of subjects through six months. The primary efficacy endpoint was a composite of: (1) Cardiac or unexplained death; (2) new Q-wave MI; and (3) detection-to-presentation time >2 h for a documented coronary occlusion event. Electrocardiogram (ECG) tracings were obtained prior to implantation, at randomization, at 1, 3, and 6 months, and at every emergency presentation to evaluate for a Q-wave MI not present at baseline. An exploratory

[42] 66 FR 55852, November 2, 2001.

[43] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[44] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients with Acute Coronary Syndrome Events. JACC, 74(16), 2047–2055.

[45] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

dual baseline ECG analysis was performed, according to the authors, because Q-waves may be transient between implantation and randomization. The dual baseline ECG analysis evaluates for the presence of new Q waves across subsequent ECGs. At the start of the trial, 456 patients were identified as controls and 451 as treated; at 6 months, 446 controls remained and 437 treated remained. The authors stated that subject enrollment ceased after 900 subjects were randomized and therefore an alpha penalty of 0.25 was taken for the interim look at event rates after 600 subjects.

According to the authors, the control and treatment groups were well matched at baseline.[46] The primary safety endpoint was met with 96.7 percent freedom (posterior probability >0.999) with a total of 31 system-related complications in 30 (3.3 percent) subjects with infections being the predominant cause of complications. The authors stated that ACS events occurrence was low. At 7, 30, 50, 70, and 90 days there were no statistical differences between the control and treated groups on the primary composite efficacy endpoint. At each time interval, the treated group had lower rates of the primary endpoint than the control group. Statistical differences were observed between treated and control groups in the dual baseline ECG exploratory analysis particularly at 50, 70, and 90 days after a confirmed occlusive event favoring the treated group. At the pre-specified 7-day look back window, the median time from the Guardian® notification to arrival at a medical facility was 51 minutes for the treated subjects as compared to 30.6 hours for control subjects (Pr [pt < pc] >0.999). Subject arrival within 2 hours of a detected and confirmed coronary occlusion occurred in 85 percent (29 of 34) of the treatment group compared with only 5 percent of the control group, with the majority of patients in the control arm presenting after 7 days. However, the authors asserted that despite a numerical reduction in new Q-wave MI using single and dual baseline ECGs at any of the pre-specified look-back windows, the posterior probability of superiority did not reach statistical significance. The applicant added that 22 percent (42/193) of the confirmed ACS events were detected due to Emergency Department (ED) visits prompted by alarms in the absence of symptoms; that silent MIs typically account for approximately 30 percent of all MIs and are historically associated with increased rates of morbidity and mortality.[47]

The second article expanded on the previously discussed study with a post hoc analysis of two coprimary efficacy endpoints: Superiority of positive predictive value (PPV) and noninferiority of false positive rate for ED visits prompted by alarms compared to symptoms-only.[48] According to the authors, these primary endpoints were assessed by comparing ED visits for an Alarms OFF group (control subjects during the randomized 6-month period) to those of an Alarms ON group (including both the treatment subjects during the first 6 months and all implanted patients beyond 6 months with alarms activated). The authors stated the expanded analysis adjudicated ED visits into either true or false-positive ACS events based on independent review of cardiac test data. The authors stated that the annual rate for Clinical Events Committee (CEC)-adjudicated ACS events was 0.151 (33 of 218.15) in the Alarms OFF group and 0.124 (193 of 1,557.64) in the Alarms ON group. In the Alarms OFF group, of the 181 ED visits, the CEC adjudicated 33 (18 percent) as ACS events (MI = 22 [67 percent]; unstable angina (UA) ¼ 11 [33 percent]), with the remaining visits adjudicated as due to either stable CAD or indeterminate etiology. The median symptom-to-door time for Alarms OFF ACS events was 8.0 h (95 percent confidence interval [CI]: 3.2 to 47.5 h). In Alarms ON subjects, of the 970 ED visits, the CEC adjudicated 193 (20 percent) as ACS events, with the remainder classified as stable CAD, indeterminate events, and/or a false-positive alarm. Of the 193 ACS events, 89 events (46 percent) were prompted by alarms (with or without symptoms; MI ¼ 40 [45 percent]; UA ¼ 49 [55 percent]). The remaining 104 visits (54 percent) were prompted by symptoms only (MI ¼ 60 [58 percent]; UA ¼ 44 [42 percent]). An overall median arrival time of 1.7 h was found for the Alarms ON group composite including all 3 prompt types for ED arrival (alarms only, alarms þ symptoms, or symptoms only), which was significantly shorter than the 8.0 h delay of the Alarms OFF group ($p < 0.0001$). The applicant asserts that the Guardian® system allows patients with asymptomatic ACS events to respond to the ED faster with a median pre-hospital delay of 1.4 hours.

The applicant further asserts that the Guardian® system offers more rapid beneficial resolution of the disease process treated because of the use of the device. According to the applicant, the Guardian® system increases the likelihood that a patient will correctly seek medical care for an ACS event in a timely manner that reduces pre-hospital delay and associated risk of heart damage (for example, larger infarct size, ejection fraction decrement)[49] [50] [51] and associated downstream sequelae. More specifically, the applicant asserts that based on the results of the second discussed study, the Guardian® system Alarms ON group showed reduced pre-hospital delays, with 55 percent (95 percent confidence interval [CI]: 46 percent to 63 percent) of Emergency department visits for ACS events <2 hours compared with 10 percent (95 percent CI: 2 percent to 27 percent) in the Alarms OFF group ($p < 0.0001$).[52] The applicant adds that results were similar when restricted to myocardial infarction (MI) events.[53] The applicant states the median pre-hospital delay for MI was 12.7 hours for Alarms OFF compared to 1.6 hours in Alarms ON subjects ($p < 0.0089$) as reported in

[46] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[47] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[48] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients with Acute Coronary Syndrome Events. JACC, 74(16), 2047–2055.

[49] Weaver WD, Cerqueira M, Hallstrom AP, *et al.* Prehospital-Initiated vs Hospital-Initiated Thrombolytic Therapy: The Myocardial Infarction Triage and Intervention Trial. JAMA. 1993;270(10):1211–1216.

[50] Hasche ET, Fernandes C, Freedman SB, Jeremy RW. Relation between ischemia time, infarct size, and left ventricular function in humans. Circulation. 1995;92:710–719.

[51] Liem AL, van 't Hof AW, Hoorntje JC, de Boer MJ, Suryapranata H, Zijlstra F. Influence of treatment delay on infarct size and clinical outcome in patients with acute myocardial infarction treated with primary angioplasty. J Am Coll Cardiol. 1998;32:629–633.

[52] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

[53] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

Holmes et al. (2019).[54] The applicant asserts that it is clinically recognized, due to numerous lines of evidence, that shorter total ischemia time is associated with better outcomes for ACS events.[55] [56] [57] [58] The applicant asserts that prompt responsiveness to symptoms and decreased pre-hospital delay is a universally understood benefit which improves the health outcomes of ACS events. According to the applicant, the American Heart Association (Mission Lifeline), American College of Cardiology (Door to Balloon (D2B) Alliance), Society for Angiographic Intervention (Seconds Count™ program) and the National Heart, Lung, and Blood Institute have organized task forces and launched national programs with the goal of improving patient awareness and response to symptoms which are indicative of potential ACS events and reducing total ischemia time (that is, prehospital delay and in-hospital delay) to improve outcomes.

The applicant next asserts the device offers more rapid beneficial resolution of the disease process because the use of the Guardian® system, as compared to the standard of care relying on symptoms alone, being in the Alarm ON group was associated with a reduction in the rate of new onset of left ventricular dysfunction.[59]

Lastly the applicant asserts the use of the Guardian® system will decrease the number of future hospitalizations or physician visits. According to the applicant, the Guardian® system reduces the annual false positive rate (FPR) of Emergency Department visits (that is, spurious ED visits where no ACS is found) by 26 percent.[60] The applicant states that the FPR for all alarms on emergency visits was 0.499 per patient-year compared to 0.678 for alarms off ($p < 0.001$).[61]

Based on the evidence submitted with the application, we have the following observations. Much of the claims for substantial clinical improvement are derived from two primary studies identified by the applicant and discussed above.[62] [63] We note that the first study (Gibson et al. 2019) did not demonstrate statistically significant superiority of the intervention during the pre-determined study window. The authors noted a lower than expected frequency of events and the study was terminated early, two factors which may have affected these results. The results from the second study are based entirely on a post hoc analysis of data from the first article. We note that the findings presented are valuable but we sought comment on whether a post hoc analysis provides sufficient evidence to support the claim of substantial clinical improvement. Furthermore, we note that the primary efficacy endpoint was a composite of three outcomes. We are not certain that this endpoint is an appropriate measure with which to evaluate substantial clinical improvement among patients experiencing ACS events. We invited public comments on whether the Guardian® system meets the substantial clinical improvement criterion.

Comment: Many commenters offered support for the approval of the Guardian®. Numerous commenters noted that according to published studies a reduction in ischemic time is associated with less cardiac damage and better outcomes for ACS events; these commenters asserted that the Guardian® brought patients to the emergency room earlier and more reliably, which resulted in better outcomes. Some commenters stated that the two studies submitted by the applicant and described in the CY 2022 OPPS/ASC proposed rule[64] [65] support the finding of a substantial clinical improvement. Some commenters noted that detection of silent MI enables the diagnosis of a medical condition that is currently undetectable, which the commenters believe is a substantial clinical improvement. Many commenters stated that the use of the Guardian® will reduce unnecessary medical utilization, will be beneficial particularly for those who experience silent myocardial infarction, and will prevent cardiac deaths. Many commenters offered patient stories that in their opinion showed that the Guardian® offers an improvement over existing treatment options. Multiple commenters noted that the Guardian® offers patients positive mental health outcomes given a reduction in experience anxiety in high-risk ACS patients. Additionally, multiple commenters stated that the total false positive rate for the ALERTS ON group was statistically less than that of the ALERTS OFF group.

One commenter stated they have been using the Guardian® for more than ten years, that the device is a valuable addition to diagnostic capabilities, and that in many cases it reduces health care utilization. A second commenter stated this technology represents a significant improvement to detecting myocardial infarction promptly. One commenter who described their experience seeing the exam prevent multiple cardiac catheterizations noted the exam is invaluable to modern medicine and that a reduction in reimbursement would threaten its realization in the appropriate context. Another commenter noted that almost all patients requested replacement of the Guardian® when it reached end of battery life, which is indicative of its safety and effectiveness.

Response: We thank the commenters for additional information to support their belief that the Guardian® device is a substantial clinical improvement over

[54] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C. M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

[55] Guerchicoff A, Brener SJ, Maehara A, *et al.* Impact of delay to reperfusion on reperfusion success, infarct size, and clinical outcomes in patients with ST-segment elevation myocardial infarction: the INFUSE–AMI Trial (INFUSE-Anterior Myocardial Infarction). JACC Cardiovasc Interv. 2014;7(7):733–740.

[56] Flynn A, Moscucci M, Share D, *et al.* Trends in door-to-balloon time and mortality in patients with ST elevation myocardial infarction undergoing primary percutaneous coronary intervention. Arch Intern Med. 2010;170(20):1842–1849.

[57] De Luca G, Suryapranata H, Zijlstra F, *et al.* Symptom-onset-to-balloon time and mortality in patients with acute myocardial infarction treated by primary angioplasty. J Am Coll Cardiol. 2003;42(6):991–997.

[58] Gersh BJ, Stone GW. Pharmacological facilitation of coronary intervention in ST-segment elevation myocardial infarction: Time is of the essence. JACC Cardiovasc Interv. 2010;3(12):1292–1294.

[59] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

[60] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[61] Ibid.

[62] Ibid.

[63] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

[64] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

[65] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

devices in existing categories or other available treatments.

Comment: The applicant asserted the Guardian® meets the second criterion for establishing a new device category, at § 419.66(c)(2), by providing a substantial clinical improvement over existing therapies because the Guardian® ''has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury compared to the benefits of a device or devices in a previously established category or other available treatment''.

The applicant pointed out that in the CY 2022 OPPS/ASC proposed rule we stated that the positive predictive value (PPV), false positive rate (FPR), and Silent myocardial infarction (MI) endpoints were reported in the ''second study'' (that is, Holmes et al.). The applicant clarified that Gibson et al. reported on both the original study analysis and the Expanded analysis, including the PPV, FPR, and Silent MI endpoints; Holmes et al. reported on pre-hospital delays and their distribution as a function of both prompt (alarm only, alarm + symptom, symptom only) and group (Alarms On vs Alarms OFF).

In response to our concerns about the primary endpoints lacking statistical significance the applicant stated both AngelMed and FDA have expressed the position that the results of the ALERTS study are best assessed using the lens that statistical significance of primary endpoints should be assessed with respect to the totality of the data. The applicant stated the endpoint analyses requested by FDA for primary endpoints during its evaluation of the study data (for example, event based or crossover analysis) reached statistical significance. The applicant added as an example that an event-based analyses of the composite primary endpoints of the original study reached statistical significance when multiple events within patients were counted, rather than relying upon a patient-based analysis in which each patient could only be counted once. According to the applicant, since multiple events may occur in a single patient, they believe that the primary endpoint data is also valid and more accurately and realistically reflects Medicare patient experiences. The applicant added that the non-primary endpoint of sustained left ventricular ejection fraction (LVEF), which was independent of the primary endpoint measures, was statistically superior (Gibson et al. 2019, p. 1924).[66] The applicant added that the Expanded analysis was explicitly designed to address the event rate seen in the original study design by leveraging the post-randomization data to derive a dataset covering an approximately three times larger study interval, which according to the applicant, greatly increased the number of events and statistical power. The applicant concluded that while not all endpoints reached statistical significance, AngelMed believes that the totality of the data supports substantial clinical improvement.

In response to our concerns about post-hoc validity, the applicant believes the Expanded analysis supports substantial clinical improvement for a number of reasons. The applicant acknowledged as noted by Gibson et al.,[67] some post-hoc analyses were done in the original analysis but that the Expanded analysis was not post-hoc. The applicant asserted the Expanded analysis was a pre-specified analysis proposed by FDA, and agreed upon by AngelMed, that was completed using data both from the original randomized period and a large amount of data from the post-randomization period. While the post-randomization data was captured with the same rigor and predefined procedures as the randomization period, the Expanded analysis increased the pool of data from less than 450 years to 1,500 years. The applicant explained that this approach was adopted by FDA and AngelMed specifically with the aim of greatly increasing the number of endpoint events and maximizing the statistical power of the Expanded analysis for the new endpoints, new definition of acute coronary syndrome (ACS), etc. The applicant added that the Expanded analysis used a new analysis protocol which resulted in data which were analyzed to obtain new, distinct, and meaningful endpoints that used clearer measurements than the ALERTS design.

Lastly, the applicant responded to our concerns regarding appropriate measure[s] with which to evaluate substantial clinical improvement. The applicant reasserted that the original analysis used a composite primary efficacy endpoint of three outcomes that provided an initial assessment of the technology. The applicant asserted that the individual components of the primary efficacy endpoint for arrival times and new Q-waves were consistently in favor of the Guardian® with arrival times reaching significance. The applicant stated, as CMS noted, in the original ALERTS analysis ''at the pre-specified 7-day look back window, the median time from the Guardian® notification to arrival at a medical facility was 51 minutes for the treated subjects as compared to 30.6 hours for control subjects (Pr [pt < pc] >0.999)'' (86 FR 42092). The applicant added these results should be combined with the Expanded analysis endpoints, which used new measures that reflected a better understanding by FDA and AngelMed for how best to evaluate the real-world impact of the Guardian System, when assessing substantial clinical improvement. The applicant asserted that more specifically, the co-primary endpoints (*i.e.,* PPV and FPR) reflected real-world performance measures that were suggested by FDA and that more accurately demonstrate, and provide a complementary view of, the clinical benefit than the composite endpoints of the original ALERTS design.

The applicant asserted that the main topics of interest for the Expanded analysis were the alarms in terms of frequency and accuracy, and how the subjects responded (*e.g.,* distribution of patient pre-hospital delay for each of the different prompts: Alarm + symptom; alarms only; or, symptom only). According to the applicant the Expanded analysis not only assessed device performance but also the behavior of the individual subjects in the Alarms ON group prompted by the alarms, symptoms or both. The applicant contended that the combination of the original study endpoints and Expanded analysis endpoints are the correct measures since these are able to show substantial clinical improvement according to multiple device pass-through criteria the ability to diagnose a medical condition that is currently undetectable, diagnose a medical condition earlier in a patient population then is currently available, decrease future hospitalizations, and improve patient outcomes.

The applicant asserted that all the ALERTS data consistently showed compelling and statistically significant reduction in pre-hospital delays in the Alarms ON group compared to the Alarms OFF group. According to the applicant, reduced total ischemic time is a correct measure for assessing substantial clinical improvement since

[66] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[67] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

it is a universal axiom that decreased delay decreases the associated risk of heart damage (*e.g.,* larger infarct size, ejection fraction decrement);[68] [69] [70] the applicant asserted that shorter total ischemic time is associated with better outcomes for ACS events.[71] [72] [73] [74] That is why, according to the applicant, multiple national agencies, including ACC, SCAI, AMA and NHLBI, have created programs specifically focused on reducing time to treatment for ACS events and have used time-based metrics as their sole assessment of provider quality for ACS care.[75] For these reasons the applicant believes that the combination of original and Expanded analysis results provides clear evidence of substantial clinical improvement for high-risk ACS patients experiencing ACS events.

Response: We appreciate the additional information provided by the commenters. In the proposed rule, we articulated tour concern about the sufficiency of a post-hoc analysis. In their public comment the applicant asserted that while some post-hoc analyses were performed, the expanded analysis was a pre-specified analysis proposed by FDA. We further appreciate the clarification from the applicant that the expanded analysis increased the number of endpoint events. Given the additional endpoints evaluated in the expanded analysis that specifically show faster visits for real events while not increasing unnecessary emergency department visits, we agree that the Guardian® system meets the substantial clinical improvement criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Guardian® would be reported with the HCPCS codes listed in the following Table 35:

TABLE 35: HCPCS CODES REPORTED WITH THE GUARDIAN®

HCPCS Code	Short Descriptor	SI	APC
0525T	Insj/rplcmt compl iims	J1	5223
0526T	Insj/rplcmt iims eltrd only	J1	5222
0527T	Insj/rplcmt iims implt mntr	J1	5222
0528T	Prgrmg dev eval iims ip	Q1	5741
0529T	Interrog dev eval iims ip	Q1	5741
0530T	Removal complete iims-	Q1	5222
0531T	Removal iims electrode only	Q1	5221
0532T	Removal iims implt mntr only	Q1	5221

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations for the CY 2022 OPPS/ASC proposed rule, we used APC 5222—Level 2 Pacemaker and Similar Procedures, which had a CY 2021 payment rate of $8,152.58 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 0527T was assigned to APC 5222 and had a device

[68] Weaver W.D., Cerqueira M., Hallstrom A.P., et al. Prehospital-Initiated vs. Hospital-Initiated Thrombolytic Therapy: The Myocardial Infarction Triage and Intervention Trial. JAMA. 1993;270(10):1211–1216.

[69] Hasche E.T., Fernandes C., Freedman S.B., Jeremy R.W. Relation between ischemia time, infarct size, and left ventricular function in humans. Circulation. 1995;92:710–719.

[70] Liem A.L., van 't Hof A.W., Hoorntje J.C., de Boer M.J., Suryapranata H., Zijlstra F. Influence of treatment delay on infarct size and clinical outcome in patients with acute myocardial infarction treated with primary angioplasty. J Am Coll Cardiol. 1998;32:629–633.

[71] Guerchicoff A., Brener S.J., Maehara A., et al. Impact of delay to reperfusion on reperfusion success, infarct size, and clinical outcomes in patients with ST-segment elevation myocardial infarction: The INFUSE–AMI Trial (INFUSE–Anterior Myocardial Infarction). JACC Cardiovasc Interv. 2014;7(7):733–740.

[72] Flynn A., Moscucci M., Share D., et al. Trends in door-to-balloon time and mortality in patients with ST elevation myocardial infarction undergoing primary percutaneous coronary intervention. Arch Intern Med. 2010;170(20):1842–1849.

[73] De Luca G., Suryapranata H., Zijlstra F., et al. Symptom-onset-to-balloon time and mortality in patients with acute myocardial infarction treated by primary angioplasty. J Am Coll Cardiol. 2003;42(6):991–997.

[74] Gersh B.J., Stone G.W. Pharmacological facilitation of coronary intervention in ST-segment elevation myocardial infarction: Time is of the essence. JACC Cardiovasc Interv. 2010;3(12):1292–1294.

[75] CMS. Timely & Effective Care. URL: *https://data.cms.gov/provider-data/topics/hospitals/timely-effective-care#heart-attack-care.*

offset amount of $1,598.72 at the time the application was received.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost for the Guardian® is 126 percent of the applicable APC payment amount for the service related to the category of devices of $8,152.58 ((10,250/8,153) * 100 = 125.7 percent). Therefore, we stated in the CY 2022 OPPS/ASC proposed rule that we believe the Guardian® meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). We stated in the CY 2022 OPPS/ASC proposed rule that the estimated average reasonable cost for the Guardian® is 641 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,598.72 ((10,250/1,599) * 100 = 641.0 percent). Therefore, we stated that we believe that the Guardian® meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. We stated in the CY 2022 OPPS/ASC proposed rule that the difference between the estimated average reasonable cost for the Guardian® and the portion of the APC payment amount for the device of $1,598.72 is 106 percent of the APC payment amount for the related service of $8,152.58 (((10,250 − 1,599)/8,153) * 100 = 106.1 percent). Therefore, we explained that we believe that the Guardian® meets the third cost significance requirement. In the CY 2022 OPPS/ASC proposed rule we invited public comment on whether the Guardian® meets the device pass-through payment criteria, including the cost criterion for device pass-through payment status.

Comment: The applicant stated the Guardian® meets the three cost criteria at § 419.66(d), consistent with CMS' analysis.

Response: We appreciate the applicant's input and agree that the Guardian® meets the cost criterion for device pass-through payment status.

After considering the public comments we received and our review of the device pass-through application, we have determined that the Guardian® system meets the criteria for device pass-through. Therefore, we are finalizing approval for device pass-through payment status for the Guardian® system effective beginning January 1, 2022.

(2) BONEBRIDGE Bone Conduction Implant System

MED–EL Corporation submitted an application for a new device category for transitional pass-through payment status for the BONEBRIDGE Bone Conduction Implant System (hereinafter referred to as the BONEBRIDGE) by the March 2021 quarterly deadline for CY 2022. The BONEBRIDGE is a transcutaneous, active auditory osseointegrated device that replaces the function of the damaged outer or middle ear and can help people for whom hearing aids are ineffective or not recommended. According to the applicant, the device consists of a bone conduction implant and electronics components, and an externally worn audio processor. The bone conduction implant is called the BONEBRIDGE Bone Conduction Implant (BCI 602) and the externally worn audio processor is called the SAMBA 2 Audio Processor. The BCI 602 consists of two main sections, the coil section and the transducer section. The BCI 602 consists of a magnet surrounded by the receiver coil, the transition, the Bone Conduction Floating Mass Transducer (BC–FMT), and the electronics package in a hermetic housing. The SAMBA 2 Audio Processor is 30.4 mm x 36.4 mm x 10.2 mm and weighs 9.3g, including the battery and magnet (strength 1). It has an 18-band digital equalizer, 18 independent compression channels, and an audio frequency range of 250 Hz to 8kHz. The audio processor is powered by a non-rechargeable 675 zinc-air button cell with a nominal 1.4-volt supply and 600mA-Hrs of capacity offering the user up to 133 hours (8 to 10 days) on a single battery.

The applicant stated that the bone conduction implant is surgically attached to the skull, is subcutaneous, and is connected to the external audio processor by transcutaneous magnetic attraction. The external audio processor picks up sound from the environment and converts those sounds to a radiofrequency (RF) signal that can be transmitted across the skin to the implant. The implant converts the signal to controlled vibrations which are conducted via the skull and perceived as sound. More specifically, the applicant stated that the BCI 602 is activated by placing the external audio processor over the magnet of the BCI 602. The signal and the energy to drive the BC–FMT are transferred via an inductive link to the internal coil, and then relayed to the BC–FMT. The BC–FMT transduces the signal into mechanical vibrations, which are conducted to the skull via the cortical titanium screws. These vibrations stimulate the auditory system through the bone conduction pathway to allow the patient to hear.

With respect to the newness criterion at § 419.66(b)(1), FDA granted a *de novo* request classifying the BONEBRIDGE as a Class II device under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act on July 20, 2018. The BONEBRIDGE is indicated for use in the following patients: (1) Patients 12 years of age or older; and (2) patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 45 dB HL; (3) Bilateral fitting of the BONEBRIDGE is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies; (4) Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (that is, single-sided deafness or ''SSD''). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz); (5) The BONEBRIDGE for SSD is also indicated for any patient who is indicated for an air conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS. Prior to receiving the device, it is recommended that an individual have experience with appropriately fit air conduction or bone conduction hearing aids. We received the application for a new device category for transitional pass-through payment status for the BONEBRIDGE on December 10, 2020, which is within 3 years of the date of the initial FDA marketing authorization. In the CY 2022 OPPS/ASC proposed rule, we invited public comments on

whether the BONEBRIDGE meets the newness criterion.

We did not receive any comments in regard to whether the BONEBRIDGE meets the newness criterion at § 419.66(b)(1). Because we received the BONEBRIDGE application on December 10, 2020, which is within 3 years of the FDA premarketing approval date of July 20, 2018, which is within 3 years, we have concluded that the BONEBRIDGE meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the BONEBRIDGE is integral to the service provided, is used for one patient only, comes in contact with human skin and is surgically implanted or inserted. The applicant also claimed that the BONEBRIDGE meets the device eligibility requirements of § 419.66(b)(4) because it is not equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

Additionally, the BONEBRIDGE is not subject to the hearing aid exclusion at § 411.15(d)(1). The BONEBRIDGE Bone Conduction Implant (BCI 602) component is an osseointegrated implant, surgically attached to the skull that converts a radiofrequency signal from an external audio processor to controlled vibrations which are conducted via the skull to the cochlea. Therefore, we explained in the CY 2022 OPPS/ASC proposed rule that we believe the BONEBRIDGE meets the criterion at § 411.15(d)(2)(i) and is not subject to the hearing aid exclusion. In accordance with the Medicare Benefit Policy Manual, Chapter 16 ''General Exclusions from Coverage,'' section 100, certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare as prosthetic devices. These include osseointegrated implants, that is, devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer. We believe the BONEBRIDGE device meets the criteria for this benefit category. We invited public comments on whether the BONEBRIDGE meets the eligibility criteria at § 419.66(b) as well as the criterion at § 411.15(d)(2)(i).

Comment: One commenter agreed with CMS that BONEBRIDGE is not subject to the hearing aid exclusion at § 411.15(d)(1).

Response: We did not receive any comments on whether the BONEBRIDGE meets the eligibility criteria at § 419.66(b)(3) or § 419.66(b)(4). We agree with the applicant that the BONEBRIDGE device meets the criteria of § 419.66(b). We believe discussion concerning § 411.15(d)(2)(i) is beyond the scope of the discussion here.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

The applicant stated that the previous device category, L8690 (Auditory osseointegrated device, includes all internal and external components), which was in effect from January 1, 2007 through December 31, 2008 does not appropriately describe the BONEBRIDGE. The applicant stated that at the time the category was established, BONEBRIDGE did not exist and the devices described by the category included auditory osseointegrated implant (AOI) devices or bone-anchored hearing aids (BAHAs). The applicant claimed that AOI devices and BAHAs are distinct from the BONEBRIDGE because they are implant systems composed of an external sound processor connected via a percutaneous abutment to a titanium implant that is implanted in the skull. In these devices, the titanium implant protrudes through the skin creating a titanium post, which directly attaches to an external sound processor. The system replaces the function of the middle ear by transmitting mechanical energy from the external transducer/sound processor directly to the titanium implant to the cochlea thereby resulting in better hearing. The applicant stated that the titanium abutment used by percutaneous systems permanently pierce the skin to allow the sound processor to transmit sound and create vibrations within the skull that stimulate the nerve fibers of the inner ear. The applicant also stated that in the percutaneous systems, the external component (sound processor) receives and processes the sound and generates the vibrations.

The applicant claimed that the BONEBRIDGE is a new technology compared to the AOI devices and BAHAs and unlike these devices, it does not use a percutaneous abutment. The applicant described BONEBRIDGE as an active, transcutaneous device that consists of a completely implanted transducer and electronics components, and an externally worn audio processor. The active implant is surgically attached to the skull, is subcutaneous, and is connected to the external audio processor by transcutaneous magnetic attraction. The external audio processor picks up sound from the environment and converts those sounds to a radiofrequency (RF) signal that can be transmitted across the skin to the implant. The implant converts the signal to controlled vibrations, which are conducted via the skull and perceived as sound. The applicant proposed the device pass-through category descriptor ''Auditory osseointegrated device, transcutaneous, with implanted transducer and radiofrequency link to external sound processor'' and suggested that L8690 be revised to read, ''Auditory osseointegrated device, percutaneous, includes all internal and external components''. The applicant stated that the Cochlear Osia®2 System, which also submitted a device pass-through application for CY 2022, would also be described by the proposed additional category.

Web stated in the CY 2022 OPPS/ASC proposed rule that we believe that the BONEBRIDGE is described by L8690 —Auditory osseointegrated device, includes all internal and external components. The applicant has noted differences between the BONEBRIDGE and the devices that were described by L8690, specifically percutaneous, auditory osseointegrated devices, regarding the connection between the implanted transducer and the external audio processor (percutaneous abutment vs. transcutaneous magnetic attraction). However, we believe that there is a similar mechanism of action for all these devices specifically, vibratory stimulation of the skull to stimulate the receptors in the cochlea (inner ear). Further, we believe that the broad descriptor for L8690 of ''Auditory osseointegrated device, includes all internal and external components'' includes the applicant's device.

In the CY 2022 OPPS/ASC proposed rule, we invited public comment on whether the BONEBRIDGE meets the device category criterion.

Comment: One commenter stated they do not support CMS' position that the BONEBRIDGE and Osia® 2 system should not be granted a new category, because these devices take much longer to implant surgically than percutaneous bone conduction implants, they are active sound processors, and they work differently than percutaneous devices like the BAHA or Oticon implants.

Another commenter who also disagreed with CMS that the BONEBRIDGE and Osia® 2 system are

adequately described by L8690 stated that the BONEBRIDGE and Osia® 2 system are transcutaneous hearing implants, and that CMS should create a new HCPCS code that describes both the procedure and the implant for these devices. The commenter expressed their disappointment in what they described as CMS' continual resistance to conduct rulemaking specifically on Middle Ear Implants (MEIs) because they believe CMS should hear the opinions of clinical experts, physicians, and Medicare beneficiaries regarding the appropriateness of classifying MEIs as prosthetic implants.

A different commenter supported CMS' conclusion in the proposed rule that BONEBRIDGE and Cochlear Osia® are appropriately described by a pass-through category previously in effect

Two commenters stated that CMS must support the inclusion of middle ear implants in the prosthetic category. The commenters asserted that not including these devices denies beneficiaries access to all FDA-approved hearing prosthetics and discourages in new technology for the hearing impaired.

Response: We appreciate the input provided by these commenters. We have taken this information into consideration in our determination of the eligibility criterion at § 419.66(c)(1), discussed below. We note some of the comments, those addressing hearing prosthetics, are outside of the scope of this rule.

Comment: The applicant stated that BONEBRIDGE is not appropriately described by the previous device category L8690, ''Auditory osseointegrated device, includes all internal and external components''. The applicant asserted that even though the mechanism of action is the same (that is, replacing the function of the middle ear by transmitting mechanical energy from the external transducer/audio processor to the cochlea), there are significant differences between BONEBRIDGE and the devices described by the previous category of L8690, ''Auditory osseointegrated device, includes all internal and external components'' that enable BONEBRIDGE to furnish a substantial clinical improvement over existing technology. According to the applicant, L8690 was established in 2007 at a time when the technology to fully implant a transducer did not exist; the devices for which L8960 was established were percutaneous passive devices.

According to the applicant, FDA created a new device classification for active implantable bone conduction hearing systems in response to BONEBRIDGE's application in 2018 (21 CFR 874.3340) which is specifically for active systems as opposed to passive systems (21 CFR 874.3300). According to the applicant, FDA's description of active implantable bone conduction is that the transducer is implanted and the description of the technical method refers to the transcutaneous nature of the technology. The applicant stated that while they recognize that FDA and CMS classify devices differently for different purposes, they believe that the way FDA classifies bone conduction implants reinforces why CMS should distinguish active implantable bone conduction devices from passive, percutaneous systems for purposes of transitional pass-through payment status.

The applicant asserted that CMS has modified broadly worded device categories to recognize technological advances within a device class and to grant transitional pass-through payment status to the newer technologies. According to the applicant, in the neurostimulator category, the original descriptor of HCPCS code C1767 was ''Generator, neurostimulator (implantable).'' The applicant asserted that CMS modified this descriptor to ''Generator, neurostimulator (implantable), non-rechargeable'' to create a new device category and grant transitional pass-through payment status for rechargeable neurostimulators described by HCPCS codes C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system) and C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system). The applicant added that CMS previously recognized differences in transluminal angioplasty catheters to support transitional pass-through payment status (for example, C2623, C1885, and C1725). The applicant asserted the new pass-through device category code should specifically describe active devices, which are those that have a fully implanted transducer attached transcutaneously to the external audio processor. The applicant suggested: CXXXX (Active auditory osseointegrated device, transcutaneous, requires implanted transducer and radiofrequency link to external sound processor). The applicant further suggested that CMS could refine L8960 to (*Passive* auditory osseointegrated device, *percutaneous or transcutaneous,* includes all internal and external components (new language underlined)). The applicant concluded that effective on January 1, 2022 there will be new and revised CPT codes that differentiate the surgical procedures for osseointegrated implants by the type of attachment (for example, 69X50 (Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor), 69X51 (Revision/replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor)), 69717 (Revision/replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor), and 69X51 (Revision/replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor).

Response: After consideration of the public comments we received, we agree there is no existing pass-through payment category that appropriately describes the BONEBRIDGE. The BONEBRIDGE device consists of an external processor that receives sound pressure energy and converts this to a radiofrequency signal which communicates with a surgically implanted subcutaneous transducer/actuator which is osseointegrated into the skull with screws. The transducer/actuator converts this signal to mechanical vibrations that are transmitted to the skull and inner ear. As stated by the applicant, when the existing pass-through category, Auditory osseointegrated device (L8690), was issued in 2007, the technology to implant the transducer/actuator did not exist. Based on this information, we have determined that the BONEBRIDGE meets the eligibility criterion at § 419.66(c)(1). Due to the similarity between the devices, we refer the reader to section IV(A)(2)(b)(4) of this rule for a similar discussion of the Osia®2 system.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough

Devices Program and has received FDA marketing authorization. With respect to the substantial clinical improvement criterion, the applicant stated that the BONEBRIDGE represents a substantial clinical improvement because it provides a reduced rate of device-related complications and a more rapid beneficial resolution of the disease process treated because of the use of the device compared to currently available treatments. The applicant submitted six studies to support these claims. The applicant also submitted references for four retrospective case studies of complications with percutaneous devices, specifically BAHAs, including infections, pain, soft tissue hypertrophy, loss of osseointegration, and need for further surgery. These studies did not involve the applicant's device.

In support of the claim that the BONEBRIDGE reduced the rate of device-related complications compared to currently available treatments, the applicant submitted a white paper that reviewed the literature reporting on safety outcomes in bone conduction implants authored by the manufacturer of the BONEBRIDGE, MED–EL.[76] The review included five products used to treat conductive hearing loss, mixed hearing loss or single side deafness, which were either percutaneous systems that had an abutment that permanently pierced through the skin or transcutaneous systems without permanent skin penetration. The authors further defined the products as either active or passive, depending on the placement of the vibrating (or active) device component. According to the authors, active bone conduction systems, the active device component, is located within the implantable part of the system. According to the authors, passive bone conduction systems, the vibrating device component, is located outside of the skull.[77]

The literature review compared the safety outcomes of the BAHA Connect and the Ponto, (passive, percutaneous systems,) the BONEBRIDGE, (an active, transcutaneous systems), and the Sophono Alpha and the BAHA Attract, (passive, transcutaneous systems). In total, 156 studies were included in the literature review. There were seven studies with 234 patients reported on the Ponto, thirteen studies with 175 patients reported on the BONEBRIDGE, twelve publications with 143 patients reported on the Sophono Alpha, seven studies reported on the BAHA Attract system with 114 patients, and 117 studies reported on the BAHA Connect system with a total of 6,965 patients. Of all reported adverse events, 38 percent were major and 62 percent were minor. Major adverse events reported in the review included revision surgery, explantation, removal at patient request, implant loss, implant device failure, skin revision surgery or skin infection. Minor adverse events included skin infections, soft tissue reactions, and healing difficulties. The results showed that 9.8 percent of patients using the BONEBRIDGE system experienced an adverse event (major or minor), compared to 68.4 percent of BAHA Attract patients, 46.9 percent of Sophono Alpha patients, 44.0 percent of Ponto system patients and 51.7 percent of BAHA Connect patients. When comparing the percentage of patients who experienced a major adverse event, 2.9 percent of BONEBRIDGE patients had a major adverse event compared to 1.8 percent of BAHA Attract patients, 4.2 percent of Sophono Alpha patients, 5.1 percent of Ponto system patients, and 21.1 percent of BAHA Connect patients.

To support the claim that the BONEBRIDGE reduced the rate of device-related complications compared to currently available treatments, the applicant also submitted a systematic review of the current literature on safety, efficacy and subjective benefit after implantation with the BONEBRIDGE device.[78] The systematic review assessed 39 publications and included randomized controlled trials, clinical controlled trials and cohort studies, case series and case reports investigating subjective and objective outcomes. In the 39 publications included in the review, 487 participants were evaluated; 303 participants had conductive hearing loss, 67 participants had mixed hearing loss, and 53 participants had single-sided deafness. The mean age of the patients in the included studies was 35.6±16.9 years. Using the guidelines available from the Cochrane Collaboration, a search strategy and review protocol was developed using PubMed (MEDLINE) and Cochrane databases to identify all publications on the BONEBRIDGE from 2012 to October 31, 2018. The researchers excluded studies that assessed a device or treatment other than the BONEBRIDGE, did not include human participants, focused on a type of hearing loss other than the losses that BONEBRIDGE is indicated for (that is, conductive hearing loss, mixed hearing loss or single-sided deafness), did not report on safety or performance/quality of life data, were not related to hearing loss or treatment thereof, lacked sufficient information for evaluation, and included overlapping samples.

The outcomes extracted from the studies were assessed via meta-analysis. The safety of the device was assessed by collecting information on complications during surgery and adverse events in the postoperative period. Of the 39 identified studies, there were 25 studies that reported on safety during a mean period of 11.7 months (range 3–36 months). The reported complications were categorized into minor and major complications, with a major complication described as requiring surgical attention leading to revision surgery or explantation. Minor complications included skin edema or erythema, skin infections, and hematomas. Out of 286 ears implanted with the device, there were no complications in 259 ears (90.6 percent). Minor complications occurred in 22 ears (7.7 percent) over a cumulative period of reported mean follow-up of 12.7 years (mean: 11.7 months ± 4.5). Major complications occurred in three studies comprising five ears (1.7 percent).[79]

The applicant submitted an additional study by Schmerber, et al. to support the claim that the BONEBRIDGE reduced the rate of device-related complications compared to currently available treatments.[80] The study of 28 participants was a multicenter, prospective study with intra-subject measurements with the purpose of the study to validate the safety and efficacy of the BONEBRIDGE 12 months after implementation. The study included nine university hospitals, seven in France and two in Belgium. Sixteen participants with conductive or mixed hearing loss with bone-conduction hearing thresholds under the upper limit of 45 dB HL for each frequency from 500 to 4000 Hz, and 12 participants with SSD (contralateral hearing within normal range) were enrolled in the study. Three of the 28 participants (with mixed or conductive hearing loss) did not complete the study; one requested that the device be removed (due to ''severe psychological problems'') and two were lost to follow

[76] MED–EL Medical Electronics. (2019). Safety outcomes of bone conduction implants: A systematic review [White paper].

[77] Ibid.

[78] Magele, A., Schoerg, P, Stanek, B. *et al.* (2019). Active transcutaneous bone conduction hearing implants: Systematic review and meta-analysis. *PLoS ONE* 14(9); e0221484 *https://doi.org/10.1371/journal.pone.0221484*.

[79] Ibid.

[80] Schmerber, S., Deguine, O., Marx, M. *et al.* (2017). Safety and effectiveness of the Bonebridge transcutaneous direct-drive bone-conduction hearing implant at 1-year device use. *Eur Arch Otorhinolaryngol* 274: 1835–1851 doi 10.1007/s00405–016–4228–6.

up. The skin safety of the participants was evaluated by the surgeon who implanted the device up to 12 months post-operatively using an ordinal scale (''very good'', ''good'', ''acceptable'', ''bad skin condition'') and a visual analogue scale (between 1 and 10 from ''very bad'' to ''excellent'') to rate cutaneous tolerance. In the study, no complications or device failures occurred, no revision surgery was necessary and no skin injury was reported. The scoring was judged as 'excellent' or 'good' for all subjects (n = 25), corresponding to scores 8 to 10 on the scale. No complication (0 percent) was observed [95 percent confidence interval = (0 percent–14.9 percent)]. The authors stated that there was a lower rate of complications for the BONEBRIDGE device compared to percutaneous systems, like the BAHA, whose complication rate was up to 24 percent in a large series of 602 ears and a revision surgery rate of 12 percent.[81] [82]

The applicant also submitted a study by Siegel et al. as evidence to support the claim that the BONEBRIDGE reduced the rate of device-related complications compared to currently available treatments.[83] The study was a retrospective review that included 37 adult patients with conductive/mixed hearing loss who met the indications for use and were implanted with BONEBRIDGE over a 5-year period from April 2013 to May 2018. Patient charts were reviewed for surgical outcomes and complications over the 6-year period. The mean time of follow-up was 32 months (range: 9–71 months). There were no events of surgical complications in the patients included in the study, specifically no instances of dural injury, cerebrospinal fluid (CSF) leak, or intracranial bleeding. There were also no skin complications and no postoperative symptoms of tinnitus/vertigo or dizziness.[84]

In support of the assertion that the use of BONEBRIDGE resulted in a more rapid beneficial resolution of the disease process compared to currently available treatments, the applicant also referenced the Magele et al., and Siegel et al. studies as well as a study conducted by Yang et al.[85] [86] [87]

As previously noted, the Magele et al. study assessed 39 publications that included 487 participants; 303 participants had conductive hearing loss, 67 participants had mixed hearing loss, and 53 participants had single-sided deafness.[88] Functional gain was available for analysis from 14 articles and was measured as the difference between unaided and aided (with the BONEBRIDGE) warble tone thresholds. On average, functional gain of 32.7 dB ±16dB was observed. Overall, the results showed a 30.89 dB (95 percent CI 27.53 dB–34.24 dB) improvement at speech presentation level; for the 30 conductive hearing loss patients, the improvement was 39.48 dB (95 percent CI 35.25 dB − 43.71 dB); for the mixed hearing loss group, the improvement was 29.08 dB (95 percent CI 26.32 dB—31.83 dB) and the improvement was 28.94 dB (95 percent CI 16.92 dB—40.96 dB) for the 10 subjects with single-sided deafness.

The applicant also noted the study by Siegel et al. to support the claim that the use of BONEBRIDGE resulted in a more rapid beneficial resolution of the disease process compared to currently available treatments.[89] As previously stated, in this study, 37 adult patients with conductive/mixed hearing loss who met the indications for use were implanted with BONEBRIDGE over a 6-year period. The patients' charts were reviewed for surgical outcomes and complications over the 6-year period. Preoperative air conduction (AC), preoperative bone conduction (BC), and 3-month postoperative aided thresholds were recorded. Speech perception was assessed using two different tests, consonant-nucleus-consonant (CNC) words and AzBio sentences. Pure-tone averages (PTAs; measured at 0.5, 1.0, 2.0 and 3.0 kHz), air-bone gap (ABG), and functional gain (FG) were calculated. The preoperative air-bone gap was calculated as the difference between AC thresholds and BC thresholds of the implanted ear. The postoperative ABG was calculated as the difference between the preoperative BC and postoperative BONEBRIDGE aided thresholds measured at 3 months postoperatively. Functional gain was calculated as the difference between preoperative AC thresholds and BONEBRIDGE aided thresholds measured 3 months postoperatively.

The results of this study showed audiological improvement in the 37 patients with a functional gain (averaged over 4 frequencies, 500 kHz to 3000 kHz) of 40.3 dB (±19.0 dB) for air conduction 3 months postoperatively. The difference between the average air to bone conduction gap fell from 44.9 dB preoperative to 4.6 dB three months after surgery. The postoperative air conduction thresholds for the 21 patients with mixed hearing loss ranged between 30–40 dB and the air conduction thresholds for the 16 patients with conductive hearing loss ranged between 20–30 dB. For patients with mixed hearing loss, nearly a full ABG closure was achieved at all frequencies by 3 months postoperatively.

In the same study, speech perception testing was available for 21 patients (57 percent). At activation, mean speech perception results for CNC words (13 patients) and AzBio sentences (14 patients) were 79 and 93 percent, respectively. At six months postoperatively, CNC words (17 patients) and AzBio sentences (21 patients) were 81 and 93 percent, respectively. The authors stated that the results of the study were comparable with what has been accomplished using traditional percutaneous conduction devices and passive transcutaneous bone conduction devices.

Lastly, to support the claim that the use of the BONEBRIDGE resulted in a more rapid beneficial resolution of the disease process, the applicant submitted a study that compared the use of the BONEBRIDGE with a non-implantable bone conduction hearing aid (BCHA).[90] This single center, prospective study involved 100 patients in Beijing, China with bilateral congenital microtia-atresia (CMA). The patients had a mean age of 11.9 ± 6.0 years old at the time the BONEBRIDGE was implanted. All patients had worn the passive bone anchored hearing aid for at least a year prior to the implantation of the BONEBRIDGE and patients were tested

[81] Schmerber, S., Deguine, O., Marx, M. *et al.* (2017). Safety and effectiveness of the Bonebridge transcutaneous direct-drive bone-conduction hearing implant at 1-year device use. *Eur Arch Otorhinolaryngol* 274: 1835–1851 doi 10.1007/s00405–016–4228–6.

[82] Hobson, J.C., Roper, A.J., Andrew, R., Rothera, M.P., Hill, P., Green, K.M. (2010) Complications of bone-anchored hearing aid implantation. *J Laryngol Otol* 124(2):132–136. doi:10.1017/S0022215109991708.

[83] Siegel, L.H., You, P., Zimmerman, K. *et al.* (2020). Active transcutaneous bone conduction implant: Audiometric outcomes following a novel middle fossa approach with self-drilling screws. *Otol Neurotol* 41(5): 605–613. *doi: 10.1097/MAO.0000000000002597.*

[84] Siegel, L.H., You, P., Zimmerman, K. *et al.* (2020). Active transcutaneous bone conduction implant: Audiometric outcomes following a novel middle fossa approach with self-drilling screws. *Otol Neurotol* 41(5): 605–613. *doi: 10.1097/MAO.0000000000002597.*

[85] Ibid.

[86] Ibid.

[87] Ibid.

[88] Ibid.

[89] Siegel, L.H., You, P., Zimmerman, K. *et al.* (2020). Active transcutaneous bone conduction implant: Audiometric outcomes following a novel middle fossa approach with self-drilling screws. *Otol Neurotol* 41(5): 605–613. *doi: 10.1097/MAO.0000000000002597.*

[90] Yang, J., Chen, P., Zhao, C. *et al.* 2020. Audiological and subjective outcomes of 100 implanted transcutaneous bone conduction devices and preoperative bone conduction hearing aids in patients with bilateral microtia-atresia. *Acta Oto-Laryngologica* 140(6): 667–673 *https://doi.org/10.1080/00016489.2020.1762929.*

an average of 25 weeks after surgery. Measured outcomes in the study included sound field thresholds (SFT), functional gain (FG) [aided threshold minus the unaided threshold], word recognition, speech reception thresholds (SRT), preoperative and postoperative bone and air conduction and patient subjective satisfaction. Bone conduction of pure tones at any frequency did not change significantly from preoperative to postoperative testing. The mean bone-conduction pure-tone threshold (PTA) before implantation was 8.7 ± 6.1 dB HL and after surgery was 8.9 ± 5.6 dB HL ($p > .745$, paired t-test). Furthermore, bone conduction did not significantly change at any frequency after surgery ($p > .05$, t-test). The mean SFT of the BONEBRIDGE (61.6 ± 7.1 dB HL) was significantly higher than the BCHA (31.3 ± 6.1 dB HL) (paired t-test, $p < .001$) and the SFT was significantly better with BONEBRIDGE at 500, 1000, 2000, and 4000 Hz sound frequencies (paired t-test, $p < .002$). Further, the FG of the BONEBRIDGE (31.2 ± 9.5 dB HL) was significantly better than the FG of the BCHA (26.5 ± 10.3 dB HL) (paired t-test, $p < .001$). The FG measured at 250 Hz in the two aided conditions had less improvement compared to other frequencies ($p < .001$). A comparison of BCHA and BONEBRIDGE resulted in a significant difference in word recognition (68.0 percent for monosyllabic words and 79.0 percent for disyllabic words with the BCHA vs. 78.0 percent for monosyllabic and 84.0 percent for disyllabic words with the BONEBRIDGE) in favor of the BONEBRIDGE ($p < .001$).

Regarding the applicant's evidence of substantial clinical improvement, we noted in the CY 2022 OPPS/ASC proposed rule that the studies submitted did not involve a direct comparison to other currently available treatments, namely percutaneous or passive, transcutaneous auditory osseointegrated devices. Therefore, we explained that it was difficult to determine whether the BONEBRIDGE provided a substantial clinical improvement over existing devices. We also indicated that the studies submitted included a small number of participants which may affect the generalizability of the data provided in support of the device.

In the white paper by MED–EL, the authors compared the complication rates associated with various studies that differed by design, population characteristics and follow-up time. We explained in the CY 2022 OPPS/ASC proposed rule we are not confident that differences seen or elucidated by the applicant are due to the differences in treatments or instead due to differences in study characteristics. Additionally, although the overall, both major and minor, adverse event ratio was significantly lower for the BONEBRIDGE device (9.8 percent) versus other bone conduction hearing devices in the study, we noted that when comparing the percent of patients who experienced a major adverse event, BONEBRIDGE patients had a major adverse event (2.9 percent) that was more comparable to other devices included in the paper. With regard to the Yang et al. study, given the young age of the patients and the congenital nature of the hearing loss being treated, we stated in the proposed rule that we are concerned that these results may not be generalizable to the Medicare population, which tends to be significantly older in age and potentially less likely to have hearing loss related to congenital causes. We invited public comments on whether BONEBRIDGE meets the substantial clinical improvement criterion.

Comment: The applicant submitted a comment in response to CMS' concerns regarding the lack of direct comparison to existing technology; differences in adverse events; and small number of study participants in the studies submitted to illustrate that BONEBRIDGE meets the substantial clinical improvement criterion. In response to CMS' concern about a direct comparison to existing technology, the applicant stated that direct head-to-head trials are not necessary or appropriate in this situation. According to the applicant, differences in the devices make a blinded randomized controlled trial impossible. The applicant asserted that while a non-blinded randomized trial would be possible, it is unclear what additional data would be gained from that approach because the applicant believed the pass-through application already contained extensive, robust, and definitive data to support that BONEBRIDGE is a substantial clinical improvement over existing technologies. The applicant asserted that enrolling patients in a head-to-head trial in which the primary difference is expected to be adverse events associated with one treatment arm is extremely challenging.

The applicant stated that the studies on BONEBRIDGE that were submitted with the pass-through application are primarily controlled case series and case reports. The applicant asserted that because the submitted studies used measures of device performance and adverse events that are consistent with studies of other devices, they allowed for direct comparison between different devices which demonstrate that BONEBRIDGE represents a substantial improvement over other bone conduction technology by achieving comparable performance in hearing improvement with fewer adverse events.

In regard to CMS' concerns about differences in adverse events, the applicant agreed with CMS that the occurrence of both overall and minor adverse event ratio was significantly lower for BONEBRIDGE than other devices but disagreed with CMS' characterization of the major adverse event rate. The applicant stated that major adverse events are far less common across all devices, including BONEBRIDGE, than minor events.

Next the applicant responded to CMS' concern that the small number of study participants could affect the generalizability of the data provided and that, because of the young age of the patients and the congenital nature of the hearing loss being treated, the study results may not be generalizable to the Medicare population. The applicant stated that BONEBRIDGE is indicated for patient who are 12 years or older, with conductive or mixed hearing loss and still can benefit from sound amplification, and who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (*i.e.,* single-sided deafness or ''SSD''). The applicant stated that the study sample sizes (and overall number of patients in those studies) are consistent with the anticipated number of implantations. The applicant stated that while the typical BONEBRIDGE patient is expected to be under age 65, several studies included patients of Medicare age and the experience of those patients was consistent with overall experience. The applicant concluded that the studies are generalizable to the Medicare population and reflective of expected results in the indicated population generally. Lastly, the applicant asserted the otologic community has accepted and adopted active transcutaneous devices as the standard of care for implanted bone conduction devices.

Response: We appreciate the additional information from commenters' about the BONEBRIDGE device but note that none of the commenters provided new empirical evidence that demonstrates that BONEBRIDGE is a substantial clinical improvement over existing treatment options. Based on our review of the study evidence, the only purported differences between BONEBRIDGE and predicate technologies relate to the major and minor adverse events from the respective technologies. Based on the information we have, it appears that

while there is a difference amongst the rates of minor adverse event incidence favoring BONEBRIDGE, patients had a major adverse event occurrence (2.9 percent) that was comparable to other devices included in the provided evidence. While the incidence of minor adverse events (*e.g.,* skin infections, soft tissue reactions, and healing difficulties) may benefit BONEBRIDGE, we believe these are less impactful on patient outcomes as compared to the incidence of major adverse events (*e.g.,* revision surgery, explantation, removal at patient request, implant loss, implant device failure, skin revision surgery or skin infection) which is comparable to previous technologies. We maintain our concerns listed in the proposed rule, that the studies submitted included a small number of participants which may affect the generalizability of the data provided in support of the device, and the applicant's comparison of outcome data across multiple studies as opposed to direct comparisons controlling for confounding variables. Because of these reasons, we do not believe that BONEBRIDGE represents a substantial clinical improvement relative to existing therapies currently available. After consideration of the public comments we received and our review of the device pass-through application, we are not approving BONEBRIDGE for transitional pass-through payment status in CY 2022 because the product does not meet the substantial clinical improvement criterion. Because we have determined that BONEBRIDGE does not meet the substantial clinical improvement criterion, we are not evaluating whether the device meets the cost criterion.

(3) Eluvia™ Drug-Eluting Vascular Stent System

Boston Scientific Corporation submitted an application for device pass-through status for the Eluvia™ Drug-Eluting Vascular Stent System (the Eluvia™ system) for CY 2022. According to the applicant, the Eluvia™ system is a combination product composed of an implantable endoprosthesis, a non-bonded freely dispersed drug layer (a formulation of paclitaxel contained in a polymer matrix), and a stent delivery system indicated for the treatment of symptomatic de novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery (PPA).

According to the applicant, the Eluvia™ system stent is a laser-cut self-expanding stent composed of nickel titanium alloy with radiopaque markers made of tantalum on the proximal and distal ends. The applicant states that the 6-French delivery system is a triaxial design with an outer shaft to stabilize the stent delivery system, a middle shaft to protect and constrain the stent, and an inner shaft to provide a guidewire lumen. The delivery system is compatible with 0.035 inch (0.89mm) guidewires and is offered in two working lengths (75 and 130 cm).

According to the applicant, peripheral artery disease (PAD) occurs when fatty or calcified material (plaque) builds up in the walls of the arteries and makes them narrower, thus restricting blood flow. The applicant asserts that when this occurs, the muscles in the legs cannot get enough blood and oxygen, especially during exertion such as exercise or walking. According to the applicant, the main symptoms of PAD are pain, burning sensation, or general discomfort in the muscles of the feet, calves, or thighs. As the disease progresses, plaque accumulation may significantly reduce blood flow through the arteries, resulting in claudication and increasing disability, with severe cases often leading to amputation of the affected limb. The applicant states that according to the Centers for Disease Control and Prevention approximately 8.5 million people age 40 and older in the United States have PAD, including 6–26 percent of individuals older than age 60.[91] According to the applicant, PAD disproportionately affects African American and American Indian populations [92] and nonrevascularized lower extremity PAD is among the most common causes of lower extremity amputation.

According to the applicant, the Eluvia™ system is designed to restore blood flow in the peripheral arteries above the knee, specifically the superficial femoral artery and proximal popliteal artery. The applicant states that the stent features a unique drug-polymer combination intended to facilitate sustained elution of the drug paclitaxel that can prevent narrowing (restenosis) of the vessel. The applicant adds that restenosis is often the cause of pain and disability for patients diagnosed with PAD.

The applicant asserts that no other endovascular technologies that are approved for the treatment of PAD provide sustained elution of a drug over at least 12 months to prevent restenosis. According to the applicant, two of the most common endovascular treatments for PAD are angioplasty and stenting. The applicant states that following an intervention within the SFA or PPA, these arteries elicit a healing response that leads to restenosis starting with inflammation, followed by smooth muscle cell proliferation and matrix formation.[93] According to the applicant, because of the unique mechanical forces in the SFA and PPA, the restenotic process can continue well beyond 12 months from the initial intervention. The applicant asserts the Eluvia™ system is designed to elute anti-restenotic drug paclitaxel beyond 12 months, which is longer than the two-month duration of drug applied from drug-coated balloons and the drug-coated stent Zilver PTX.

With respect to the newness criterion at § 419.66(b)(1), the Eluvia™ system received FDA PMA on September 18, 2018. The application for a new device category for transitional pass-through payment status for the Eluvia™ system was received on February 26, 2021, which is within 3 years of the date of the initial FDA approval or clearance. In the CY 2022 OPPS/ASC proposed rule we invited public comments on whether the Eluvia™ system meets the newness criterion.

Comment: The applicant stated that the Eluvia™ system application was submitted within three years of regulatory approval and therefore meets the newness criterion for transitional device pass-through eligibility.

Response: We appreciate the commenter's input. and agree that the Eluvia™ system meets the newness criterion because we received its device pass-through application on February 26, 2021, which is within 3 years of the September 18, 2018, the date of FDA PMA.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Eluvia™ system is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically impacted or inserted. The applicant also claimed that the Eluvia™ system meets the device eligibility requirements of § 419.66(b)(4) because it is not equipment, an instrument, apparatus, implement, or items for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. In the CY 2020 OPPS/ASC final rule with comment period, we stated that we determined that the Eluvia™ system

[91] Centers for Disease Control and Prevention. *https://www.cdc.gov/heartdisease/pad.htm.*

[92] Virani SS, et al. AHA Statistical Update: Heart Disease and Stroke Statistics-2020 Update, A Report from the American Heart Association. Circulation. 2020;141:e139–e596.

[93] Forrester JS, et al. A paradigm for restenosis based on cell biology: Clues for the development of new preventive therapies. J Am Coll Cardiol. 1991 Mar 1;17(3):758–69.

device meets the eligibility criteria at § 419.66(b)(3) and (4) in response to a pass-through application that the applicant submitted on November 15, 2018 (84 FR 61286). Because the applicant submitted a new application for device pass-through status for the Eluvia™ system, we again invited public comments on whether the Eluvia™ system continues to meet the eligibility criteria at § 419.66(b(3) and (4).

Comment: The applicant stated that the Eluvia™ system continues to meet the transitional pass-through eligibility criteria at § 419.66(b)(3) and (4) as CMS initially concluded in the CY 2020 OPPS/ASC final rule with comment period.

Response: We agree with the applicant and continue to believe that the Eluvia™ system meets the eligibility criteria at § 419.66(b)(3) and (4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We stated that we have not identified an existing pass-through payment category that describes the Eluvia™ system. The applicant proposed a category descriptor for the Eluvia™ system of ''Stent, non-coronary, polymer matrix, minimum 12-month sustained drug release, with delivery system.'' Previously, we invited public comment and subsequently determined that the Eluvia™ system device meets the device category eligibility criterion. For a complete discussion of comments received, please see the CY 2020 OPPS/ASC final rule with comment period (84 FR 61286 through 61287). We invited public comments on whether the Eluvia™ system continues to meet this criterion.

Comment: One commenter, a manufacturer of a competing product stated that CMS has reviewed drug-eluting vascular stents in the past and determined they fell into an already existing pass-through payment category. The commenter stated that in August of 2002, CMS concluded that coronary drug-eluting stents were described by existing pass-through device categories C1874 (Stent, coated/covered, with delivery system) and C1875 (Stent, coated/covered, without delivery system).[94] The commenter stated that at the time drug eluting stents were coated with paclitaxel and the same polymer currently used on the Eluvia™ system. The commenter stated that in 2012, Zilver PTX DES was denied pass-through payment status and quotes a letter received from CMS which stated, ''. . . the outpatient clinical review team believes that the Zilver PTX Stent is appropriately described by previously active device pass-through category C1874, Stent, coated/covered, with delivery system. This category describes drug-eluting stents.'' [95] According to the commenter, FDA has grouped the Eluvia™ system and Zilver PTX DES into the same product code:

> ''NIU: Stent, Superficial Femoral Artery, Drug-Eluting—a metal scaffold with a drug coating placed via a delivery catheter into the SFA to maintain the lumen. The drug coating is intended to inhibit restenosis. Class III; Cardiovascular Review Panel.''

The commenter asserted that both devices are self-expanding nitinol stents coated with the drug paclitaxel.[96] [97] The commenter further asserted that the Eluvia™ system's underlying stent platform and delivery system is the same as Boston Scientific's Innova self-expanding stent (an uncoated stent for treating the superficial femoral artery); [98] the drug paclitaxel is the same drug used on the Zilver PTX DES and earlier generation coronary drug-eluting stents; and the polymers used in the Eluvia™ system coating are the same polymers as those used in the Xience V and Promus Element coronary stents.[99] The commenter stated that this history precludes the establishment of a new device category for the Eluvia™ system.

Response: We appreciate the information provided by the commenter and have taken this into consideration in making our determination of § 419.66(c)(1), discussed below.

Comment: The applicant stated that in the CY 2020 OPPS/ASC proposed rule CMS stated that no existing device category describes the Eluvia™ system and that since that time no new categories that would describe the system have been established.

Response: We appreciate the information submitted by the commenters. Given the additional information provided by commenters CMS is concerned that the applicant's proposed long descriptor of 'Stent, non-coronary, polymer matrix, minimum 12-month sustained drug release, with delivery system'' may not suitably differentiate the Eluvia™ system from Zilver PTX. Specifically, given that CMS has previously determined that coronary drug-eluting stents were described by existing pass-through device categories C1874 (Stent, coated/covered, with delivery system) and C1875 (Stent, coated/covered, without delivery system), that FDA has classified the Eluvia™ system and Zilver PTX into the same product code, and finally that CMS previously denied pass-through status to Zilver PTX, stating that it is appropriately described by previously active device pass-through category C1874 (Stent, coated/covered, with delivery system), we believe the same pass-through category code C1874 appropriately describes the Eluvia™ system. We note that HCPCS code C1874 is agnostic to the length of time a drug is released and therefore encapsulates the Eluvia™ system's proposed long descriptor. Further, we do not believe it is appropriate for a discussion of substantial clinical improvement, *i.e.,* the length of time a drug release is maintained, to be the primary motivating determinant in a determination of whether a device meets the device category criterion in § 419.66(c)(1).

After consideration of the public comments we received, we conclude there is an existing pass-through payment category or pass-through category previously in effect that appropriately describes the Eluvia™ system. Based on this information, we have determined that the Eluvia™ system does not meets the eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With respect to this criterion, the applicant claims the Eluvia™ system provides a substantial clinical improvement over existing technologies for the following reasons: (1) The Eluvia™ system achieves superior primary patency; (2) the Eluvia™

[94] **Federal Register**/Vol. 67, No. 154/Proposed Rules/Page 52106.

[95] Correspondence with Dr. John McInnes, Director, Division of Outpatient Care.

[96] *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=1076.*

[97] *https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180011B.pdf.*

[98] Gray W, *et al.* A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet; Published Online September 22, 2018; *http://dx.doi.org/10.1016/S0140-6736(18)32262-1.*

[99] *https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180011B.pdf.*

system achieves reduced lesion revascularization, leading to a reduced rate of subsequent therapeutic interventions at one year and a statistically significant reduction of target lesion revascularization (TLR) at 2 years; (3) the Eluvia™ system decreases the number of future hospitalizations or physician visits; (4) the Eluvia™ system reduces hospital readmission rates; (5) the Eluvia™ system reduces the rate of device-related complications; and (6) the Eluvia™ system achieves similar functional outcomes and quality of life index values while associated with half the rate of TLRs.

Many of the assertions made by the applicant are derived from the IMPERIAL trial which is reported in three citations supplied by the applicant.[100] [101] [102] We discuss results from the MAJESTIC study and then these publications from the IMPERIAL study to provide context for the assertions made by the applicant.

The first article, by Müller-Hülsbeck et al., discusses the three-year results of the MAJESTIC study, the first-in-human prospective, single-arm, multicenter, clinical trial involving 57 patients with symptomatic lower limb ischemia and lesions in the superficial femoral artery or proximal popliteal artery.[103] Patients who were treated with the Eluvia™ system were followed for a 3-year time period during which they took acetylsalicylic acid as an antiplatelet therapy. At 24 months, patients received a duplex ultrasound, ankle-brachial index, and Rutherford classification at a clinical visit. At 36 months patients completed a telephone or clinical visit which included adverse event and antiplatelet medication assessments. The authors report that long-term results from the MAJESTIC study of the Eluvia™ system continue to demonstrate good technical and clinical outcomes (assessed through 2 years) and a low reintervention rate (through 3 years).

The second article, by Gray et al., discusses the IMPERIAL trial, a prospective randomized (2:1) (the Eluvia™ system vs. Zilver PTX), single-blind, non-inferiority study in 465 patients with symptomatic lower-limb ischemia manifesting as claudication with atherosclerotic lesions in the native superficial femoral artery or proximal popliteal artery across 65 centers and multiple countries.[104] Of the 465 patients enrolled, 309 were assigned to the Eluvia™ system and 156 were assigned to Zilver PTX. The authors state the overall sample size in the randomized trial was selected to preserve adequate statistical power for non-inferiority testing of the primary efficacy and safety endpoints at a prespecified, one-sided significance level of 5 percent for each, without adjustment for multiplicity.

The authors state baseline demographic, clinical, and angiographic characteristics were similar between the two study groups, indicative of successful randomization. The primary efficacy endpoint of the trial was primary vessel patency at 12 months which was a binary endpoint based on a duplex ultrasound peak systolic velocity ratio of 2.4 or lower in the absence of clinically driven target lesion revascularization or bypass of the target lesion. Secondary endpoints at 12 months were technical success, procedural success, adverse events, stent integrity, major adverse events, and clinical outcomes. The authors note that the funder of the study was involved in study design, data collection, data analysis, data interpretation, and writing of the report. To identify statistically meaningful results for the non-inferiority test, the authors used a test such as the Farrington-Manning method, to estimate the lower bound for the 95 percent CI of the difference between treatment groups.[105] According to the authors, if this lower bound was greater than the non-inferiority margin of –10 percent, the Eluvia™ system would be considered non-inferior to Zilver PTX in terms of device efficacy. For all other statistical comparisons, the authors used a p value of less than 0.05 as indicative of a significant difference.

According to the authors, the primary non-inferiority analyses were done when 409 patients (276 in the Eluvia group and 133 in the Zilver PTX group) had completed 12 months of follow-up or had a primary efficacy or safety endpoint event.[106] Primary patency was observed for 231 (87 percent) of 266 patients in the Eluvia™ system group and for 106 (82 percent) of 130 patients in the Zilver PTX stent group (difference 5.3 percent [one-sided lower bound of 95 percent CI –0.66]; $p < 0.0001$). 259 (95 percent) of 273 patients in the Eluvia group and 121 (91 percent) of 133 patients in the Zilver PTX group had not had a major adverse event at 12 months (difference 3.9 percent [one-sided lower bound of 95 percent CI –0.46]; $p < .0.0001$). According to the authors, superiority of the Eluvia™ system over Zilver PTX (primary patency in 86.8 percent vs. 77.5 percent, respectively, $p = 0.0144$) was met in the post-hoc analysis of 12 month primary patency data in the full-analysis cohort. The authors summarize by stating the proportions of patients with stent thrombosis or clinically driven target lesion revascularisation in the Eluvia stent group were about half those in the Zilver PTX group while both groups showed improvements in clinical symptoms and walking function and the occurrence of stent fracture was low.[107]

The third article, by Golzar et al, discusses the one-year follow up of the single-arm long lesion substudy portion of the IMPERIAL trial.[108] Fifty patients were enrolled in the study where 20 patients had diabetes, 16 were current smokers, 35 had moderately or severely calcified lesions, and 16 lesions were total occlusions. To be eligible, patients needed a lesion ranging from 140 mm to 190 mm which required two overlapping Eluvia stents. At 12 months, no deaths, stent thrombosis, or target limb amputation had occurred. The primary patency rate was 87.0

[100] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[101] Müller-Hülsbeck S et al. Two-Year Efficacy and Safety Results from the IMPERIAL Randomized Study of the Eluvia Polymer-Coated Drug-Eluting Stent and the Zilver PTX Polymer-free Drug-Coated Stent. Cardiovasc Intervent Radiol. 2021;44:368–375.

[102] Golzar J et al. Effectiveness and Safety of a Paclitaxel-Eluting Stent for Superficial Femoral Artery Lesions up to 190 mm: One-Year Outcomes of the Single-Arm IMPERIAL Long Lesion Substudy of the Eluvia Drug-Eluting Stent. Journal of Endovascular Therapy. 2020;27(2):296–303.

[103] Müller-Hülsbeck S, Keirse K, Zeller T, Schroe H, Diaz-Cartelle J. Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3-Year Followup. Cardiovasc Interv Ther. 2017;40(12):1832–1838.

[104] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[105] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[106] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[107] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[108] Golzar J et al. Effectiveness and Safety of a Paclitaxel-Eluting Stent for Superficial Femoral Artery Lesions up to 190 mm: One-Year Outcomes of the Single-Arm IMPERIAL Long Lesion Substudy of the Eluvia Drug-Eluting Stent. Journal of Endovascular Therapy. 2020;27(2):296–303.

percent at 12 months which exceeded the 60 percent performance goal. Forty-three patients (91 percent) had Rutherford category improvement without the need for TLR. The authors concluded that one year patency with the Eluvia™ system was independent of lesion length.

The fourth article, by Müller-Hülsbeck et al., discusses the two-year follow up to the IMPERIAL trial.[109] The authors found that through 24 months, the patency rates and Rutherford category improvements were largely sustained, with a significantly lower clinically driven TLR rate for Eluvia versus Zilver PTX at 2 years. At 2 years the TLR rate for patients treated with Eluvia was 12.7 percent as compared to patients treated with Zilver PTX at 20.1 percent (P = 0.0495). As with the previous citation, both study arms show sustained clinical improvement (that is improvement in Rutherford classification by one or more categories as compared with baseline and without TLR) of 84.4 percent for patients treated with Eluvia and 78.2 percent for patients treated with Zilver PTX (p = 0.140). For all-cause mortality, Eluvia (7.1 percent) and Zilver PTX (8.3 percent) did not statistically differ (p = 0.6649). The authors conclude that the IMPERIAL trial provides support for the benefit of drug-eluting treatment in this population.

According to the applicant, the Eluvia™ system achieves superior primary patency compared to Zilver PTX. The applicant states that, based on the IMPERIAL trial, the Eluvia™ system demonstrated superior primary patency over Zilver PTX, 86.8 percent vs. 77.5 percent, respectively (p=0.0144), based on pre-specific post-hoc analysis. The applicant further states that at 12 months, the Eluvia™ system had greater primary patency than Zilver PTX at 88.5 percent vs. 79.5 percent, respectively (p=0.0119). According to the applicant, these results are consistent with the 96.4 percent primary patency rate at 12 months in the MAJESTIC study, the single-arm first-in-human study of the Eluvia™ system.[110] Furthermore, in regard to this point, the applicant asserts among patients 65 and older, the primary patency rate in the Eluvia™ system was 92.6 percent compared to 75.0 percent in Zilver PTX (p=0.0386). Lastly, the application states that among 50 patients with an average lesion length of 162.8 mm (long lesions), each treated with two Eluvia stents, there was a 12 month primary patency of 87 percent and a TLR of 6.5 percent.[111]

According to the applicant, the Eluvia™ system reduced subsequent therapeutic interventions at one year and reduced target lesion revascularization at two years. Based on the IMPERIAL trial, the applicant asserts the Eluvia™ system achieved a substantial reduction in re-intervention with a target lesion revascularization (TLR) of 4.5 percent compared to 9.0 percent (p=0.0672) in the Zilver PTX group.[112] The applicant states that at two years the Eluvia™ system had a statistically significantly lower rate of TLRs than Zilver PTX of 12.7 percent vs. 20.1 percent, respectively (p=0.0495).[113] The applicant notes that the published analysis presented in this application has a slightly different clinically-driven TLR rate at 2 years than internal analysis provided in the Eluvia CY 2020 device pass-through application (12.7 percent and 20.1 percent (p=0.0495) vs. 12.9 percent and 20.5 percent (p=0.0472), respectively). We note that the applicant provides a table which compares TLR rates between the Eluvia™ system and Zilver PTX by all patients 65 and older, U.S. patients 65 and older, and patients with diabetes.

The applicant asserts that patients treated with the Eluvia™ system required fewer days of hospital care than in the Zilver PTX group. According to the applicant, patients treated with the Eluvia™ system had fewer days in the hospital as compared to Zilver PTX for all adverse events (13.9 vs. 17.7 respectively), TLR (2.8 vs. 7.1 respectively), and procedure and device-related adverse events (2.7 vs. 4.5 respectively). We note that statistical significance was not assessed.

The applicant asserts that patients treated with the Eluvia™ system had reduced hospital readmission rates compared to those treated with Zilver PTX at 12 months at 3.9 percent and 7.1 percent respectively (p=0.1369).[114]

The applicant asserts that while rates of adverse events were similar in total between treatment arms in the IMPERIAL trial, device-related adverse-events were reported in 8 percent of patients treated with the Eluvia™ system as compared to 14 percent of patients treated with Zilver PTX.[115]

Lastly, the applicant asserts that the Eluvia™ system is able to achieve similar functional outcomes to Zilver PTX while associated with half the rate of TLRs. The applicant states while functional outcomes appear similar between the Eluvia Stent System and Zilver PTX groups at 12 months, these improvements for the Zilver PTX group are associated with twice as many TLRs to achieve similar EQ–5D index values.[116] The applicant provides multiple tables which show similar improvements in walking, distance, speed, stair climbing, and health-related quality of life (EQ–5D) between the Eluvia™ system and Zilver PTX.

For a complete discussion of the applicant's previous submission regarding substantial clinical improvement please see the CY 2020 OPPS/ASC final rule with comment period (84 FR 61287 through 61292). We note that we did not approve the Eluvia™ system for CY 2020 transitional device pass-through payment due to the potential increased long-term mortality signal that FDA was evaluating at the time. We further note that in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58657), we discussed the FDA August 7, 2019 update, which concluded that the benefits of paclitaxel-coated devices (for example, reduced reinterventions) should be considered in individual patients along with potential risks (for example, late mortality) as well as for individual patients judged to be at particularly high

[109] Müller-Hülsbeck S et al. Two-Year Efficacy and Safety Results from the IMPERIAL Randomized Study of the Eluvia Polymer-Coated Drug-Eluting Stent and the Zilver PTX Polymer-free Drug-Coated Stent. Cardiovasc Intervent Radiol. 2021;44:368–375.

[110] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[111] Golzar J et al. Effectiveness and Safety of a Paclitaxel-Eluting Stent for Superficial Femoral Artery Lesions up to 190 mm: One-Year Outcomes of the Single-Arm IMPERIAL Long Lesion Substudy of the Eluvia Drug-Eluting Stent. Journal of Endovascular Therapy. 2020;27(2):296–303.

[112] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[113] Müller-Hülsbeck S et al. Two-Year Efficacy and Safety Results from the IMPERIAL Randomized Study of the Eluvia Polymer-Coated Drug-Eluting Stent and the Zilver PTX Polymer-free Drug-Coated Stent. Cardiovasc Intervent Radiol. 2021;44:368–375. Published online 22 November 2020.

[114] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[115] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[116] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

risk for restenosis and repeat femoropopliteal interventions, clinicians may determine that the benefits of using a paclitaxel-coated device outweigh the risk of late mortality. The applicant asserted that the Eluvia™ system has demonstrated substantial clinical improvement over Zilver PTX in the IMPERIAL trial to include no increase in all-cause mortality. In response to this new information, we no longer have concerns regarding the increased long-term mortality signal we described in the CY 2020 OPPS/ASC final rule with comment period.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61289) we noted that the IMPERIAL study, which showed significant differences in primary patency at 12 months, was designed for noninferiority and not superiority. Therefore, we were concerned that results showing primary patency at 12 months may not be valid given the study design. In response, the applicant stated that a non-inferiority study is consistent with accepted research methodology and is typical of many head-to-head trials of medical devices. For the complete discussion of this issue, please see the CY 2020 OPPS/ASC final rule with comment period (84 FR 61290).

In the CY 2022 OPPS/ASC proposed rule, we invited public comments on whether the Eluvia™ Drug-Eluting Vascular Stent System meets the substantial clinical improvement criterion.

Comment: One commenter, a manufacturer of a competitor device, asserted that Eluvia™ does not meet the substantial clinical improvement criterion. The commenter asserted that the MAJESTIC study is inadequate to demonstrate substantial clinical improvement as use of a single arm study to support this criterion is problematic due to the small (n=57) and highly selective patient population (*e.g.,* lesion length limited to a maximum of 11 cm).[117] Further, the commenter stated that despite a very high primary patency rate of 96.4 percent at 12 months the rate drops substantially to 77.9 percent at just 25 months,[118] which suggests the potential of late catch-up phenomenon as previously observed with other polymer-coated peripheral DES.[119] [120] The commenter added that the target lesion revascularization (TLR) rate appears to double each year (*i.e.,* quadruple from year 1 to year 3), increasing from 3.6 percent at 1 year to 7.2 percent at 2 years to 14.7 percent at 3 years.[121]

The commenter next asserted that errors in the data analysis have been reported in scientific meetings[122] and require a correction of the 1-year publication and results;[123] the commenter also asserted that other publications also require a correction.[124] The commenter stated that patency results are inconsistently presented and also contended that the primary endpoint of the 12-month patency study (n=409) indicate primary patency of 86.8 percent (231/266) for Eluvia vs. 81.5 percent (106/130) for Zilver PTX with the subsequent post-hoc analysis showing a larger difference of 86.8 percent (243/280) for Eluvia™ vs. 77.5 percent (110/142) for Zilver PTX. The commenter asserted that the post-hoc analysis represents an additional 14 Eluvia™ and 12 Zilver PTX patients; the commenter notes that the results for the final 12 Zilver PTX patients added to the post-hoc analysis appear to be outliers who had significantly worse outcomes than the primary patient cohort (patency 77.5 percent [110/142] in primary cohort vs. 33.3 percent [4/12] in post-hoc cohort, p=0.002) and raises doubt about the poolability of the data between these two cohorts.

The commenter also asserted that in the most recently presented 2-year results (with data correction),[125] there is no significant difference in patency between Eluvia and Zilver PTX at 2 years (83.0 percent vs. 77.1 percent, p=0.10, not significant). The commenter contended that based on these results a claim of superior primary patency cannot be maintained. The commenter was concerned by the claim of ''highest reported'' two-year primary patency, stating: (1) The modified definition of primary patency is inconsistent across multiple studies, (example, the Zilver PTX randomized trial and the IMPERIAL trial) which limits appropriate comparability; (2) the second Zilver PTX randomized trial, which had a higher 2-year primary patency rate of 83.4 percent compared with 83.0 percent for the Eluvia™ system, was excluded from the comparison; [126] and (3) the claim of superiority requires head-to-head comparative studies or at a minimum an attempt to account for differences between compared studies.

The commenter next asserted that the long-term safety of the Eluvia™ system has not been demonstrated due to: (1) A lack of long-term safety data; (2) multiple reports noting the presence of aneurysmal degeneration, peri-stent inflammation, or negative late lumen loss associated with the Eluvia™ system,; (3) the total dose and not just the density must be considered; (4) paclitaxel is released directly to the target lesion by the Zilver PTX DES and not by the Eluvia™ system; (5) avoiding use of a polymer, if possible, is a preferred stent design; and (6) long-term paclitaxel release may not be necessary or desired.

Another commenter stated that the Eluvia™ system meets the substantial clinical improvement criterion because CMS already concluded the same in the FY 2022 IPPS/LTCH final rule for new technology add-on payment.

Response: We appreciate the information provided by the commenters and have taken this into consideration when making our determination of the substantial clinical improvement criterion, discussed below.

Comment: The applicant submitted a comment in support of the substantial clinical improvement criterion. The applicant stated that in the CY 2022 OPPS/ASC proposed rule CMS referenced the FY 2021 IPPS/LTCH final

[117] Müller-Hülsbeck S, et al. Twelve-Month Results From the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Treatment of Obstructive Femoropopliteal Disease. J Endovasc Ther. 2016;23(5):701–7.

[118] Müller-Hülsbeck S, et al. Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3-Year Follow-up. Cardiovasc Intervent Radiol. 2017;40(12):1832–1838.

[119] Duda SH, et al. Drug-eluting and Bare Nitinol Stents for the Treatment of Atherosclerotic Lesions in the Superficial Femoral Artery: Long-Term Results From the SIROCCO Trial. J Endovasc Ther. 2006;13(6):701–710.

[120] Lammer J, et al. First Clinical Trial of Nitinol Self-Expanding Everolimus-Eluting Stent Implantation for Peripheral Arterial Occlusive Disease. J Vasc Surg. 2011;54(2):394–401.

[121] Müller-Hülsbeck S, et al. Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3-Year Follow-up. Cardiovasc Intervent Radiol. 2017;40(12):1832–1838.

[122] Gray WA. 2-year Outcomes from the IMPERIAL Randomized Head to Head Study of Eluvia DES and Zilver PTX. Oral presentation at: The Leipzig Interventional Course (LINC) Annual Meeting; January 2020; Leipzig, Germany.

[123] Gray WA, et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392(10157):1541–1551.

[124] Soga Y, et al. Japanese Patients Treated in the IMPERIAL Randomized Trial Comparing Eluvia and Zilver PTX Stents. Cardiovasc Intervent Radiol. 2020;43(2):215–222.

[125] Gray WA. 2-year Outcomes from the IMPERIAL Randomized Head to Head Study of Eluvia DES and Zilver PTX. Oral presentation at: The Leipzig Interventional Course (LINC) Annual Meeting; January 2020; Leipzig, Germany.

[126] Dake MD, et al. Durable Clinical Effectiveness With Paclitaxel-Eluting Stents in the Femoropopliteal Artery 5-Year Results of the Zilver PTX Randomized Trial. Circulation. 2016;133(15):1472–1483.

rule (85 FR 58657) and stated that CMS no longer has concerns about the long-term mortality signal. The applicant further stated that in the FY 2021 IPPS/LTCH final rule, CMS determined that the Eluvia™ system represents a substantial clinical improvement over existing technologies. The applicant added that despite the assessment in the FY 2021 IPPS/LTCH final rule, in the CY 2022 OPPS/ASC proposed rule, CMS asked for input regarding whether the Eluvia™ system meets the substantial clinical improvement criterion, even raising concerns that CMS agreed were not an issue in the discussion of its NTAP decision. The applicant asserted that the regulations governing the substantial clinical improvement criterion for NTAP and for transitional device pass-through status are nearly identical. The applicant asserted that in its discussion of substantial clinical improvement for the Eluvia™ system under the IPPS NTAP application, CMS found that the Eluvia™ system met the criterion based on the following endpoints: Superior primary patency; reduced rate of subsequent therapeutic interventions; decreased future hospitalizations and physician visits; reduced hospital readmission rates; reduced rate of device-related complications; and similar functional outcomes and EQ–5D index values with half the rate of target lesion revascularizations (TLRs). The applicant added that these endpoints are clinically meaningful for all patients with PAD and not just for those in the inpatient setting. The applicant asserted that there is no evidence-based rationale that would lead CMS to a reach a different conclusion regarding substantial clinical improvement for the Eluvia™ system for transitional device pass-through status versus NTAP. The applicant added that there is no difference in the indicated patient population for the Eluvia™ system based on site of service, which is determined by physicians based on the totality of a patient's condition.

Response: We appreciate the additional information provided by the commenters. We note in the FY 2021 IPPS/LTCH final rule (85 FR 58657) CMS determined that the Eluvia™ system met the substantial clinical improvement criterion after consideration of the comments received and for the reasons discussed, including the improved outcomes shown in the IMPERIAL and MAJESTIC trials as well as the updated August 7, 2019 FDA guidance in regard to paclitaxel-coated devices. As we stated in the FY 2021 IPPS/LTCH final rule, the applicant provided the following two-year results from the IMPERIAL global randomized controlled clinical trial, comparing the Eluvia™ system to Zilver® PTX®:

- The Eluvia™ system maintains higher primary patency than Zilver® PTX® at 2 years, 83.0 percent compared to 77.1 percent. The applicant contended that guidelines recognize the importance of primary patency in assessing the efficacy of peripheral endovascular therapies.[127]
- The Eluvia™ system's 2-year primary patency is the highest reported in a superficial femoral artery US pivotal trial for a drug-eluting stent or drug coated balloon.[128] Per the applicant, the 2-year primary patency results are consistent with the 2-year TLR results released earlier in 2019.[129] According to the applicant, the Eluvia™ system sustained a statistically significant reduction in TLR at 2 years compared to Zilver PTX, 12.9 percent vs. 20.5 percent (p = 0.0472).[130]
- In a subgroup analysis of patients 65 years and older (Medicare population), the primary patency rate in the Eluvia™ system stent group is 92.6 percent, compared to 75.0 percent for the Zilver® PTX® stent group (p=0.0386).

One commenter identified potential issues with the data used to evaluate the Eluvia™ system for substantial clinical improvement. In spite of the information presented by the commenter, we concur with the assessment discussed in the FY 2021 IPPS/LTCH final rule and the applicant's additional clarification concerning the specific endpoints for which they believe the Eluvia™ system meets the substantial clinical improvement criterion. We note one commenter takes issue with two of the above points that CMS relied upon in the FY 2021 IPPS/LTCH final rule in its determination of substantial clinical improvement, (*e.g.* the higher primary patency, the 2-year primary patency being the ''highest reported'', and the target lesion revascularization rate). However, based upon the data and comments received we note that the Eluvia™ system group maintained a higher primary patency rate than the Zilver® PTX® stent group (92.6 percent vs. 75.0 percent, $p < 0.05$) in the subgroup analysis of patients 65 years and older. Given this information and the information provided by the applicant and commenters in their comments, we agree that the Eluvia™ system meets the substantial clinical improvement criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that Eluvia™ system would be reported with the HCPCS codes in the following Table 36:

TABLE 36: HCPCS CODES REPORTED WITH THE ELUVIA ™ SYSTEM

HCPCS Code	Short Descriptor	SI	APC
37226	Fem/popl revasc w/ stent	J1	5193
37227	Fem/popl revasc stnt & ather	J1	5194

[127] Writing Committee Members, Gerhard-Herman MD, Gornik HL et al. 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease: Executive Summary. Vasc Med. 2017 Jun; 22(3):NP1–NP43.

[128] Highest 2-year primary patency based on 24-month Kaplan-Meier estimates reported for IMPERIAL, IN.PACT SFA, ILLUMENATE, LEVANT II and Primary Randomization for Zilver PTX RCT.

[129] BSC Data on File. As-treated ELUVIA and PTxControl data from IMPERIAL RCT.FDA PTA reference based on FDA Executive Summary (median of PTA arms).Abbreviations: DES, drug eluting stent; TLR, target lesion revascularization; PTx, paclitaxel.

[130] Boston Scientific Presentation to the Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting, June 19, 2019.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5193—Level 3 Endovascular Procedures, which had a CY 2021 payment rate of $10,042.94 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 37226 had a device offset amount of $4,843.71 at the time the application was received.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of the Eluvia™ system is 56 percent of the applicable APC payment amount for the service related to the category of devices of $10,042.94 ((5,645/10,042.94) × 100 = 56.2 percent). Therefore, we stated in the CY 2022 OPPS/ASC proposed rule that we believe the Eluvia™ system meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost for the Eluvia™ system is 117 percent of the cost of the device-related portion of the APC payment amount for the related service of $4,843.71 ((5,645/4,843.71) × 100 = 116.5 percent). Therefore, we stated in the CY 2022 OPPS/ASC proposed rule that we do not believe that the Eluvia™ system meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost for the Eluvia™ system and the portion of the APC payment amount for the device of $4,843.71 is 8 percent of the APC payment amount for the related service of $10,042.94 (((5,645 − 4,843.71)/10,042.94) × 100 = 7.98 percent). Therefore, we stated in the CY 2022 OPPS/ASC proposed rule that we do not believe that the Eluvia™ system meets the third cost significance requirement.

We invited public comments on whether the Eluvia™ system meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: A manufacturer of a competitor device and a second commenter agreed that based on calculations included in the CY 2022 OPPS/ASC proposed rule for the second and third cost significance tests, the Eluvia™ system does not meet the cost significance requirements for device pass-through payment.

A third commenter stated that in response to the CY 2021 OPPS/ASC proposed rule they noted that a device that meets the newness and substantial clinical improvement criteria for transitional pass-through payment may only replace some of the devices included in the device-related portion (DRP).

Multiple commenters asserted that the Eluvia™ system meets the cost criteria for transitional device pass-through status. The commenters stated that the current methodology of the cost significance criterion uses a single number, which includes all devices utilized in a particular procedure. The commenters explained that since the DRP contains all devices for respective claims, the DRP is artificially high as a benchmark for the Eluvia™ system since it only replaces one stent in the procedure. The commenters concluded that as a result of this issue, the Eluvia™ system does not meet the cost criteria because the average sales price of the device is not sufficient to account for all the other devices included in the DRP, and not just the stent it is replacing.

Response: We appreciate the information provided by the commenters and have taken this into consideration in making our final determination of the cost significance criterion discussed below.

Comment: The applicant agreed that the Eluvia™ system meets the first cost test. Regarding the second and third cost significance tests, the applicant stated that CMS overestimated the DRP used in the cost significance tests. According to the applicant, when calculating the OPPS payment for a procedure that uses a pass-through device, CMS has an established policy of only subtracting (as the DRP) the cost of those devices that are replaced by the transitional pass-through device. The applicant asserted that the payment policy methodology for calculating the DRP should also be applied to the calculating cost significance for the cost criteria.

The applicant asserted of the cost significance tests that the first question addresses the cost of the transitional pass-through device relative to total payment, whereas the second two questions address cases where the transitional pass-through device would replace device costs currently reflected in the associated procedure payment amount. The applicant offered three scenarios concerning candidate devices and the DRP: (1) A candidate device may replace all or nearly all of the devices that are accounted for in the DRP of the related procedures (*e.g.,* neurostimulators); (2) a candidate device may replace only some of the devices included in the DRP (*e.g.,* the Eluvia™ system); and (3) a candidate device may not replace any of the devices included in the DRP (*e.g.,* a single-use endoscope). According to the applicant, CMS' calculation of the DRP to include all the devices used in the related procedure overestimates the DRP in the latter two scenarios. The applicant asserted that because of this novel technologies that otherwise meet the transitional pass-through criteria would fail the cost significance tests since they will be compared to the cost of all devices used in a procedure and manufacturers may establish higher device prices to exceed an inflated DRP.

The applicant asserted that CMS' current approach to calculating the DRP is contrary to the intent of the TPT program, which is to recognize the costs associated with novel, clinically beneficial technologies that are not yet incorporated into the procedural cost calculation with temporary, separate device-related payment until the new device cost is reflected in rate setting data. The applicant added, the intent of the DRP in the cost significance test is to compare the cost of the pass-through candidate device to the costs of the device(s) that the pass-through candidate device would replace and not to compare the costs of the candidate device to the total costs of all devices used in a procedure to include those that are unrelated and not replaced by the candidate device.

Next the applicant stated that in its discussion of the pass-through device offset policy for OPPS payment in the CY 2004 Outpatient Prospective Payment System (OPPS) Final Rule, CMS stated, ''Beginning with the implementation of the 2002 OPPS update (April 1, 2002), we deduct from the pass-through payments for the identified devices an amount that offsets the portion of the APC payment amount that we determine is associated with the

device, as required by section 1833(t)(6)(D)(ii) of the Act.''[131] The applicant continued, ''We will apply an offset to a new device category only when we are able to determine that an APC contains costs associated with the new device. We will also continue our existing methodology for determining any offset amount if we find that device costs associated with a new device category are packaged into the APCs. We will include information about any applicable offset in the transmittal we issue to announce information regarding the new category''.[132]

The applicant stated that on at least two occasions, CMS has referenced the above-stated policy in decisions not to apply a device offset when calculating payment for pass-through devices. The applicant cited two instances where they believe CMS has chosen to not apply a device offset, first with C2623 (Drug coated angioplasty balloon)[133] and C1748 (Single use [disposable] endoscope).[134] According to the applicant, with these two decisions, CMS has acknowledged that it does not consider the cost of devices that are not replaced by the pass-through device when calculating the pass-through payment amount. The applicant asserted that given these decisions and the associated payment policy, CMS has not only shown that it has the authority to define the DRP calculation methodology, but it has also established a precedent for defining the DRP as only those devices that are replaced by the pass-through device. The applicant stated that it is therefore inconsistent for CMS to apply a different DRP methodology in the cost test for devices seeking transitional pass-through payment.

According to the applicant the prior precedents and this inconsistency are central to the application of the TPT cost significance test for the Eluvia™ system. The applicant stated that as requested in their 2018 transitional pass-through application submission, they again ask CMS to consider only the cost of those devices replaced by the Eluvia™ system when calculating the DRP for CPT Code 37226 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed). According to the applicant the average femoral, popliteal stent placement procedure (CPT 37226) includes ancillary (non-stent) device costs of $2,311.26 and average stent device costs of $3,406.93. The applicant asserts then that a more appropriate comparison is of the Eluvia™ system to the $3,406.93 in average stent device costs. The applicant contends that the non-stent devices should not be considered in the DRP utilized in the 3-part cost significance test because the Eluvia™ system is not replacing these costs associated with the non-stent devices. The applicant concluded that should the $3,406.93 be used as the DRP, then the Eluvia™ system passes the second and third cost significance tests at approximately 166 percent and 22 percent, respectively.

Response: As we stated above in section IV.2.a. of this final rule with comment period, to be eligible for device pass-through payments a device must have an average cost that is not ''insignificant'' relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d). Since the CY 2017 OPPS/ASC final rule (81 FR 79648 through 79649), CMS has described the manner in which it evaluates device pass-through applicants against the cost significance criterion at § 419.66(d). Per the applicant, CMS has stated in prior rules that we will deduct from the pass-through payments for a device an amount that offsets the portion of the APC payment amount that we determine is associated with the device. Once a device is approved for pass-through payments CMS appropriately applies this rationale to determine the payment rate for devices with pass-through status. However, except in rare circumstances, CMS has consistently applied the full device offset amount associated with the applicable APC used to evaluate the cost significance tests at § 419.66(d). In this manner we believe we are identifying devices whose average cost is not ''insignificant''.

In reference to the prior precedents identified by the applicant (C2623 and C1748) where CMS determined to not apply an offset we disagree with the applicant's conclusion that these situations apply to the Eluvia™ system and the request for a partial device offset. In some cases, CMS determines that none of the costs of a new device are included in the applicable APC. For example, in the CY 2021 OPPS/ASC final rule (85 FR 85994), CMS determined for the EXALT™ Model D Single-Use Duodenoscope that the costs associated with the device were not already reflected in the device portions of APCs 5303 (Level 3 Upper GI Procedures) or 5331 (Complex GI Procedures) because there were no single-use duodenoscopes on the market previously so no operating cost data associated with such devices could be included in the historical OPPS claims data. Additionally, *none* of the costs associated with the device were reflected in the device portions of the applicable APCs. This is similarly reflected in the CMS transmittal 10541 dated December 31, 2020 where CMS stated, ''we have determined that the costs associated with C1748 are not already reflected in APCs 5303 or 5331''.[135]

In its comment to CMS, the applicant asserts that the Eluvia™ system replaces a portion of the previous related devices and not all of previous related devices. This is further evidenced by the applicant's request for a partial device-related portion (that is, device offset) of $3,406.93. CMS has historically used a full device offset related to the applicable APC in the majority of cases when assessing the cost criterion; to our knowledge CMS has never utilized a partial device offset in this manner. If CMS desired to change the cost criterion evaluation it must do so through notice and comment rulemaking to provide ample notice and an opportunity for public comment. Therefore, we do not believe the use of a partial device offset, as the applicant has requested, would be consistent with CMS' application of the cost significance criterion specified at § 419.66(d). Because the applicant did not meet the second and third cost significance tests, we do not believe the Eluvia™ system meets the cost significance criterion specified at § 419.66(d).

After consideration of the public comments we received and our review of the device pass-through application, we are not approving the Eluvia™ system for transitional pass-through payment status in CY 2022 because the product does not meet the cost significance criterion.

(4) Cochlear™ Osia® 2 System

Cochlear Americas submitted an application for a new device category

[131] Department of Health and Human Services. Centers for Medicare & Medicaid Services. 42 CFR parts 410 and 419. [CMS–1471–FC]. **Federal Register**. 2003;68(216): 63438–9.

[132] Department of Health and Human Services. Centers for Medicare & Medicaid Services. 42 CFR parts 410 and 419. [CMS–1471–FC]. **Federal Register**. 2003;68(216): 63439.

[133] CMS Transmittal 3280 (R3280CP, June 5, 2015) *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3280CP.pdf.*

[134] CMS Transmittal 10541 (R10541CP, December 31, 2020) *https://www.cms.gov/files/document/r10541cp.pdf.*

[135] CMS Transmittal 10541 (R10541CP, December 31, 2020) *https://www.cms.gov/files/document/r10541cp.pdf.*

for transitional pass-through payment status for the Cochlear™ Osia® 2 System (hereinafter referred to as the Osia® 2 System) by the December 2020 quarterly deadline for CY 2022. The Osia® 2 System is a transcutaneous, active auditory osseointegrated device that replaces the function of the middle ear by providing mechanical energy to the cochlea. According to the applicant, the device consists of four components including: (1) An external sound processor, the Osia 2 Sound Processor; (2) the Osia OSI200 Implant Piezo Power™ transducer; (3) the BI300 osseointegrated implant for anchoring and single point transmission; and (4) a fixation screw for attaching the OSI200 implant to the BI300 implant which is implanted in the skull.

The external sound processor captures environmental sounds and converts the sound signal into a digital signal transmitted as a radiofrequency. The external sound processor also contains a magnet and a battery (rechargeable 675 zinc air button 1.4Volt; 600 mA-hrs capacity). The magnets couple the external and internal components across the skin. The transducer (Piezo Power™) detects the radiofrequency signals after they pass through the intact skin and transforms the signal to vibrations, which are then transmitted to the bone-implanted fixation screw. The screw vibrates the skull bone (temporal portion) which stimulates the cochlea (inner ear) to transmit the information to the brain so that the vibrations are perceived as sounds. The implanted portion is 7.2 cm x 3 cm x 0.49 cm. The system has a fitting range of 55 dB sensory neural hearing loss. The applicant stated that unlike hearing aids, which make sounds louder, an auditory osseointegrated device, such as the Osia® 2 System can improve clarity of hearing and improve hearing at higher frequencies.

With respect to the newness criterion at § 419.66(b)(1), the Osia® 2 System received FDA 510(k) clearance on November 15, 2019, based on a determination of substantial equivalence to a legally marketed predicate device. The Osia® 2 System is intended for the following patients and indications: (1) Patients 12 years of age or older; (2) patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 55 dBHL; (3) Bilateral fitting of the Osia® 2 System is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies; (4) patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (that is, single-sided deafness or ''SSD''). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz). The Osia® 2 System for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS. Prior to receiving the device, it is recommended that an individual have experience with appropriately fitted air conduction or bone conduction hearing aids.

We received the application for a new device category for transitional pass-through payment status for the Osia® 2 System on December 1, 2020, which is within 3 years of the date of the initial FDA marketing authorization. We invited public comments on whether the Osia® 2 System meets the newness criterion.

Comment: The applicant asserted that the Osia® 2 system is new because it received FDA clearance on November 15, 2019 and its predicate device received FDA clearance on July 3, 2019, both of which are within 3 years of December 1, 2020, the date on which we received the device pass-through application for the Osia® 2 System. The applicant asserted that the predicate to these devices, the BONEBRIDGE System, received FDA authorization on July 20, 2018 which is also within the newness period for transitional pass-through status.

Response: We appreciate the applicant's input and agree that the Osia® 2 system meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Osia® 2 System is integral to the service provided, is used for one patient only, comes in contact with human skin, and is surgically implanted or inserted. The applicant also claimed that the Osia® 2 System meets the device eligibility requirements of § 419.66(b)(4) because it is not equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We invited public comments on whether the Osia® 2 System meets the eligibility criteria at § 419.66(b).

We did not receive public comments in regard to whether the Osia® 2 system meets the eligibility criteria at § 419.66(b)(3) or § 419.66(b)(4), therefore we agree with the applicant that the Osia® 2 system meets the criteria of § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

The applicant stated that the Osia® 2 System differs significantly from the devices that were included in the previous category for auditory osseointegrated devices (L8690—Auditory osseointegrated device, includes all internal and external components) which was effective from effective from January 1, 2007 through December 31, 2008. The applicant claimed that the devices that were described by this category include a transducer/actuator and sound processor that is worn externally with the transducer/actuator connected to the skull by a percutaneous post or abutment that penetrates the skin. In these devices, the sound processor converts sound into a digital signal which the transducer/actuator converts to vibrations that are transmitted to the skull through the abutment. The vibrations are transmitted directly to the inner ear and are reproduced as sound.

The applicant stated that the Osia® 2 System is distinct from devices with a percutaneous connection between the transducer and the sound processor because the transducer/actuator for the Osia® 2 system is surgically implanted and has a magnetic transcutaneous attachment to the external sound processor. The applicant also claimed that the percutaneously coupled osseointegrated devices included in the previous device pass-through category convert sound to mechanical vibrations in the external sound processor/actuator, then transmit the vibrations to the internal components. The applicant claimed that the Osia® 2 system instead converts the sound to mechanical vibrations after it has reached the internal components. The applicant claimed that the technology to fully implant the transducer/actuator did not exist when the previous device pass-through category was established. The applicant proposed the device pass-

through category descriptor ''Auditory osseointegrated device, including implanted transducer/actuator with radiofrequency link to external sound processor''. The applicant stated that the BONEBRIDGE Bone Conduction Implant System, which also submitted a device pass-through application for CY 2022 and is described in this section under number (2) above, would also be described by the proposed additional category.

We stated in the CY 2022 OPPS/ASC proposed rule that we believe that the Osia® 2 system is described by L8690—Auditory osseointegrated device, includes all internal and external components. The applicant has noted differences between the Osia® 2 system and the devices that were described by L8690, specifically percutaneous, auditory osseointegrated devices, regarding the connection between the implanted transducer and the external audio processor (percutaneous abutment vs. transcutaneous magnetic attraction) however, we believe that there is a similar mechanism of action for all these devices specifically, vibratory stimulation of the skull to stimulate the receptors in the cochlea (inner ear). Further, we believe that the broad descriptor for L8690 of ''Auditory osseointegrated device, includes all internal and external components'' includes the applicant's device. In the CY 2022 OPPS/ASC proposed rule, we invited public comment on whether the Osia® 2 system meets the device category criterion.

Comment: We received multiple comments addressing § 419.66(c)(1) for both BONEBRIDGE and the Osia® 2 system. One commenter stated they do not support CMS' position that the BONEBRIDGE and Osia® 2 system should not be granted a new category, because these devices take much longer to implant surgically than percutaneous bone conduction implants, they are active sound processors, and they work differently than percutaneous devices like the BAHA or Oticon implants.

Another commenter who also disagreed with CMS that the BONEBRIDGE and Osia® 2 system are adequately described by L8690 stated that the BONEBRIDGE and Osia® 2 system are transcutaneous hearing implants, and that CMS should create a new HCPCS code that describes both the procedure and the implant because both are new. The commenter expressed their disappointment in what they described as CMS' continual resistance to conduct rulemaking specifically on Middle Ear Implants (MEIs) because they believe CMS should hear the opinions of clinical experts, physicians, and Medicare beneficiaries regarding the appropriateness of classifying MEIs as prosthetic implants.

A different commenter stated their support for CMS' conclusion in the proposed rule that BONEBRIDGE and Cochlear Osia® are appropriately described by a pass-through category previously in effect.

Two commenters stated that CMS must support the inclusion of middle ear implants in the prosthetic category. The commenters asserted that not including these devices denies beneficiaries access to all FDA-approved hearing prosthetics and discourages in new technology for the hearing impaired.

Response: We appreciate the input provided by these commenters. We have taken this information into consideration in our determination of the eligibility criterion at § 419.66(c)(1), discussed below. We note some of the comments, those addressing hearing prosthetics, are outside of the scope of this rule. Please refer to the above section (2) BONEBRIDGE where we summarize these comments in full.

Comment: One commenter stated that the pass-through category identified by CMS, L8690, does not provide an accurate description of the Osia® 2 system as it does not account for several material differences that exist between Osia (and other active auditory osseointegrated implant (AOI) systems) and the devices intended to be described by L8690. The commenter asserted that the mechanism by which the vibrations are generated and reach the skull are entirely different, which is reflected by the FDA device classification. The commenter asserted that L8690, developed in 2007, could not account for active devices.

Response: We appreciate the information provided by the commenter and have taken this into account in our determination of the § 419.66(c)(1) eligibility criterion, discussed below.

Comment: The applicant stated that L8690 does not describe active, transcutaneous systems like Osia® 2 and BONEBRIDGE. First, the applicant stated that L8690 did not extend to active, transcutaneous active osseointegrated implants (AOIs) when it was created in 2007 because the only osseointegrated implant at that time was passive and percutaneous. Second, the applicant, responding to CMS' statement, ''that there is a similar mechanism of action for all these devices . . .'' [136], stated that the mechanism by which the vibrations are generated and reach the skull are entirely different and can affect safety, clinical outcomes, and patient quality of life. The applicant asserted that the active nature of the Osia® 2 system, which diminishes skin-related complications associated with percutaneous devices and at the same time improves audiological outcomes, differs from passive systems which involve the transmission of mechanical vibrations from the external components to the internal components. As opposed to previous technologies, the applicant asserted that active systems incorporate a new mechanism of action that sends digital signals from the external sound processor to the internal components, which then convert a digital signal to a vibration directly at the point of bone contact, eliminating the need for percutaneous attachment. The applicant stated that although both active and passive systems ultimately generate a vibration to stimulate the cochlea, the way they do so and where the vibration is generated are entirely different. The applicant added that FDA created a new device classification for active implantable bone conducting hearing systems in response to BONEBRIDGE's application in 2018 (21 CFR 874.3340), which is specifically for active systems as opposed to that for passive systems (21 CFR 874.3300). The applicant stated that while they recognize that FDA and CMS classify devices differently for different purposes, they believe that the way FDA classifies bone conduction implants reinforces why CMS should distinguish active implantable bone conduction devices from passive, percutaneous systems for purposes of transitional device pass-through payment status.

The applicant next stated that in other situations, CMS has modified broadly worded device categories to recognize technological advances within a device class. The applicant noted that the descriptor for HCPCS code C1767—''Generator, neurostimulator (implantable)''—was modified to ''Generator, neurostimulator (implantable), non-rechargeable'' to create a new device pass-through category for HCPCS codes C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system) and C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system).

Response: After consideration of the public comments we received, we agree there is no existing pass-through payment category that appropriately describes the Osia® 2 system. The Osia® 2 system device consists of an external

[136] 86 FR at 42104.

processor that receives sound pressure energy and converts this to a radiofrequency signal which communicates with a surgically implanted subcutaneous transducer/actuator via a stud. The transducer/actuator converts this signal to mechanical vibrations that are transmitted to the skull and inner ear. As stated by the applicant, when the existing pass-through category, Auditory osseointegrated device (L8690), was issued in 2007, the technology to implant the transducer/actuator did not exist. Based on this information, we have determined that the Osia® 2 system meets the eligibility criterion at § 419.66(c)(1). Due to the similarity between the devices, we refer the reader to section IV(A)(2)(b)(2) of this rule for a similar discussion of the BONEBRIDGE.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization. With respect to the substantial clinical improvement criterion, the applicant stated that the Osia® 2 system represents a substantial clinical improvement because it provides a reduced rate of device-related complications compared to currently available treatments. The applicant submitted five references to retrospective case series that studied the long-term complications associated with percutaneous osseointegrated bone conduction hearing devices, specifically bone-anchored hearing aids.[137] [138] [139] [140] [141] The applicant stated that complications associated with bone-anchored hearing aids include irritation and/or infection of the skin surrounding the abutment, skin flap necrosis, wound dehiscence, bleeding or hematoma formation, soft tissue overgrowth and persistent pain.[142] [143] [144] [145] [146] Additionally, the applicant also submitted five references to clinical studies and case series involving the use of transcutaneous osseointegrated bone conduction hearing devices. Of these five references, three of these studies involved the use of the BONEBRIDGE device and have been previously discussed in this section, one study that involved the use of the BAHA Attract device, and one study that involved the use of the Osia® system, an earlier version of the Osia® 2 system.

In support of their claim that the Osia® 2 system reduced the rate of device-related complications compared to currently available treatments, the applicant submitted a multicenter prospective within-subject study conducted at five centers in Europe, Australia, and USA. This study investigated clinical performance, safety, and benefit of the Osia® system and included 51 adult subjects with mixed and conductive hearing loss (MHL/CHL, n=37) and single-sided sensorineural deafness (SSD, n=14). In regard to safety outcomes, patients experienced the following minor adverse events including pain (n=7), numbness (n=1), vertigo (n=3), swelling (n=3), tension implant site (n=1), warmth at the SP site (n=3), headache (n=3), hematoma/bleeding (n=2).[147] One participant developed an implant-site infection three days after implantation, which subsequently developed into skin necrosis and dehiscence. The implant had to be removed 55 days after implantation.

In the CY 2022 OPPS/ASC proposed rule, we expressed concern that the applicant did not submit studies that involved the use of the Osia® 2 system to demonstrate substantial clinical improvement of the device. The applicant submitted one study that investigated the Osia® system that utilizes an earlier model of the device. We explained in the proposed rule that we were concerned that the evidence of substantial clinical improvement submitted by the applicant did not directly compare the Osia® 2 system to other currently available treatments, namely percutaneous or passive, transcutaneous auditory osseointegrated devices. Therefore, in the CY 2022 OPPS/ASC proposed rule we explained that we were concerned that we are unable to determine a substantial clinical improvement of the Osia 2 system as compared to existing devices. We stated that we would be interested in any additional studies that involve the use of the Osia® 2 system and compare the device to other currently available auditory osseointegrated devices. We invited public comments in the CY 2022 OPPS/ASC proposed rule on whether the Osia® 2 system meets the substantial clinical improvement criterion.

Comment: In response to our concerns about whether the Osia® 2 system meets the substantial clinical improvement criterion, one commenter stated that head-to-head comparisons are not a requirement for transitional pass-through status. The commenter added that because the Osia® 2 System and its predecessor system are substantially similar as determined by FDA, the clinical evidence for the predecessor system applies equally to the Osia® 2 System. The commenter asserted that the clinical evidence submitted by the applicant, as described by CMS in the CY 2022 OPPS/ASC proposed rule, supports that the Osia® 2 System is a substantial clinical improvement compared to percutaneous systems.

Response: We thank the commenter for the information and have taken it into consideration in our determination of whether the Osia® 2 System meets the substantial clinical improvement, discussed below.

Comment: The applicant submitted a comment in support of its position that the Osia® 2 System meets the substantial clinical improvement criterion. The applicant contended, based on the discussion in the CY 2022 OPPS/ASC proposed rule, that CMS does not appear to be concerned that there is insufficient evidence to conclude that active/transcutaneous systems are a substantial clinical improvement over passive/percutaneous systems. Rather, the applicant believes our concerns relate to the fact that

[137] Kraai T, Brown C, Neeff M, Fisher K. Complications of bone-anchored hearing aids in pediatric patients. Int J Pediatr Otorhinolaryngol. 2011 Jun;75(6):749–53.

[138] Badran K, Arya AK, Bunstone D, Mackinnon N. Long-term complications of bone-anchored hearing aids: a 14-year experience. J Laryngol Otol. 2009 Feb;123(2):170–6.

[139] House JW, Kutz JW Jr. Bone-anchored hearing aids: incidence and management of postoperative complications. Otol Neurotol. 2007 Feb;28(2):213–7.

[140] Asma A, Ubaidah MA, Hasan SS, Wan Fazlina WH, Lim BY, Saim L, Goh BS. Surgical outcome of bone anchored hearing aid (baha) implant surgery: A 10 years experience. Indian J Otolaryngol Head Neck Surg. 2013 Jul;65(3):251–4.

[141] Shirazi MA, Marzo SJ, Leonetti JP. Perioperative complications with the bone-anchored hearing aid. Otolaryngol Head Neck Surg. 2006 Feb;134(2):236–9.

[142] Ibid.

[143] Ibid.

[144] Ibid.

[145] Ibid.

[146] Ibid.

[147] Mylanos, E.A.M., Hua, H., Arndt, S. 2020. Multicenter clinical investigation of a new active osseointegrated steady-state implant system. *Otol Neurotol* 41: 1249–1257.

evidence was submitted for Osia® 1 and not Osia® 2.[148]

In response to CMS' concerns, the applicant stated that first, head-to-head trials are not a requirement for demonstrating substantial clinical improvement for purposes of qualifying for transitional pass-through device—status and would not be appropriate in this situation. First, the applicant stated that enrolling patients in a head-to-head trial in which the primary difference is expected to be adverse events associated with one treatment arm is extremely challenging, and it is unclear what additional data would be gained, particularly since the nature and frequency of device-related complications between passive percutaneous and transcutaneous devices is established and commonly reported in the literature. Second, the applicant stated that clinical studies involving the first Osia® device are applicable to the Osia® 2 System because the devices are substantially equivalent and only minor differences exist between the two versions of the device. The applicant notes that the FDA 510(k) clearance for the Osia® 2 system expressly noted clinical performance data did not reveal significant differences in hearing performance between either system and did not raise new issues of safety or effectiveness.

Next the applicant discussed two studies that involve the Osia® 2 system. The first study reported the surgical and audiological experience with the Osia 2 System based on a U.S. nationwide controlled market release (CMR) conducted between December 9, 2019 and February 14, 2020 involving 23 surgeons who performed 44 operations on 43 recipients.[149] The applicant noted that no device-related complications were reported and five complications not associated with the Osia® 2 system were reported that were all successfully resolved. According to the applicant, the authors concluded that the Osia® 2 system, ''. . . represents an important advance in hearing implant technology. Utilizing innovative digital piezoelectric stimulation, this active auditory osseointegrated implant (OSI) delivers high-power output and improved high frequency gain for optimizing speech perception while maintaining safety and engendering high patient satisfaction.'' [150]

The second study is a systematic review that, according to the applicant, provides evidence of substantial clinical improvement for both the Osia® and Osia® 2 systems.[151] According to the applicant, the authors reported their findings from reviewing adverse event reports associated with active transcutaneous bone conduction implants (atBCls) in the Manufacturer and User Facility Device Experience (MAUDE) database of FDA. According to the applicant, after removing irrelevant reports and duplicates, 83 MDRs describing 91 adverse events (patient injuries and device malfunctions) were analyzed, all of which occurred postoperatively. The applicant asserted that the five most comment types of events, device malfunctions leading to a lack of conduction or hearing (n=26, 29 percent), infections (n=14, 15 percent), device malfunctions of intermittent or reduced hearing (n=12, 13 percent), and pain and wound formation (n=9 or 10 percent), accounted for 77 percent of all events reported. The applicant asserted that device malfunctions were predominantly associated with BONEBRIDGE (93 percent of all device malfunctions reported), while patient injuries such as infections were more commonly reported for Osia® (67 percent of all reported injuries). According to the applicant, the authors concluded that complications observed with active transcutaneous BCI use are similar to those with passive transcutaneous BCIs.[152]

In regard to evidence submitted with their application, the applicant stated commonly reported adverse events which include ear inflammations, dizziness, and headache, are clearly not related to the implantation. Based on reported events in a comparison between the Osia® system [153] and the Baha Connect System [154] the applicant asserted that it is clear that the Osia® System has significantly lower rates of implantation-related adverse events than the passive/percutaneous system.

Response: We thank the applicant for their submission and the additional information provided. Because of the overlap between comments for the Osia® 2 system and BONEBRIDGE, we direct readers to section (IV)(2)(b)(2)(2) of this final rule with comment period.

We appreciate the commenters' responses on the Osia®2 system application. We disagree with the applicant's comment that commonly reported adverse events which include ear inflammations, dizziness, and headache, are clearly not related to the implantation. We note, the term ''dizziness'' can be used to explain a variety of symptoms that can include weakness, lightheadedness, unsteadiness and vertigo, and an argument against causality may be reasonable. ''Headache'', however, is pain affecting the head or face. To dismiss a possible connection between the skull implantation procedure and a complaint of post-procedure headache does not seem reasonable.

While new evidence was submitted by the applicant which attempts to address substantial clinical improvement for the Osia® 2 system, we are unable to conclude that the device meets the substantial clinical improvement criterion. Specifically, we note that the results of a meta-analysis are informative, however without controlling for the differences across studies (for example, study design, sampling technique, etc.) we are unable to determine if the treatment effects seen are due to the Osia® 2 system or due to differences in study design. In regard to commenter's suggestion that a head-to-head analysis not being required for an assessment of substantial clinical improvement, we agree in part. While it may be the case that a direct head-to-head comparison may not always be feasible or appropriate, we acknowledge that this is the ideal manner in which to address comparisons between one technology and another. For example, CMS utilized meta-analyses and historical controls as evidence of substantial clinical improvement when robust critical efforts have been made to account for variations in study design (*i.e.,* confounding) in the former and comprehensive reviews to establish the validity of the latter. In regard to the second study [155] discussed in the applicant's comment, we note that the small sample size of 43 recipients and 44 procedures may not be generalizable to a larger Medicare beneficiary population. Therefore, we are unable to determine a substantial clinical

[148] 86 FR at 42,105.

[149] Goldstein MR, Bourn S, Jacob A. Early Osia® 2 bone conduction hearing implant experience: Nationwide controlled-market release data and single-center outcomes.

[150] Ibid.

[151] Crowder HR, Bestourous DE, Reilly BK. Adverse events associated with Bonebridge and Osia bone conduction implant devices. Am J Otolaryngol. 2021 ;42(4):102968. doi:10.1016/j.amjoto.2021.102968 PubMed ID: 33676070.

[152] Ibid.

[153] Mylanus EAM et al. in the submission; Clinica/Trials.gov Identifier: NCT03086135.

[154] van Hoof M et al. 2020, PubMed JD: 32231633; Clinica/Trials.gov Identifier: NCT01796236.

[155] Goldstein MR, Bourn S, Jacob A. Early Osia® 2 bone conduction hearing implant experience: Nationwide controlled-market release data and single-center outcomes.

improvement of the Osia® 2 system as compared to existing devices.

After consideration of the public comments and additional information we have received, we are not approving the Osia® 2 system for transitional pass-through payment status in CY 2022 because the product does not meet the substantial clinical improvement criterion. Because we have determined that the Osia® 2 system does not meet the substantial clinical improvement criterion, we have not evaluated the cost criterion.

(5) Pure-Vu® System

Motus GI submitted an application for a new device category for transitional pass-through payment status for the Pure-Vu® System (Pure-Vu®) for CY 2022. The applicant asserted that the Pure-Vu® System helps to avoid aborted and delayed colonoscopy procedures due to poor visualization of the colon mucosa by creating a unique High Intensity, Pulsed Vortex Irrigation Jet that consists of a mixture of air and water to break-up fecal matter, blood clots, and other debris, and scrub the walls of the colon while simultaneously removing the debris through two suction channels. The applicant stated that the suction channels have a sensor to detect the formation of a clog in the channels, triggering the system to automatically purge and then revert to suction mode once the channel is clear. According to the applicant, this combination of the agitation of the fluid in the colon via the pulsed vortex irrigation and simultaneous removal of the debris allows the physician to visualize the colon and achieve a successful colonoscopy or other advanced procedure through the colonoscope even if the patient is not properly prepped and has debris either blocking the ability to navigate the colon or covering the colon wall obscuring the mucosa and any pathology that may be present. The applicant asserted that the constant volume suction pumps do not cause the colon to collapse, which allows the physician to continue to navigate the colon while cleansing and avoids the need to constantly insufflate the colon, which may be required with other colonoscopy irrigation systems.

The applicant stated that the Pure-Vu® System is comprised of a workstation that controls the function of the system, a disposable oversleeve that is mounted on a colonoscope and inserted into the patient, and a disposable connector with tubing (umbilical tubing with main connector) that provides the interface between the workstation, the oversleeve, and off the shelf waste containers.

The applicant explained that the workstation has two main functions: Cleansing via irrigation and evacuation, and acting as the user interface of the system. The applicant explained that the irrigation into the colon is achieved by an electrical pump that supplies pressurized gas (air) and a peristaltic pump that supplies the liquid (water or saline). According to the applicant, the pressurized gas and liquid flow through the ''main connector'' and are mixed upon entry into the umbilical tubing that connects to the oversleeve. The applicant explained that the gas pressure and flow are controlled via regulators and the flow is adjusted up or down depending on the cleansing mode selected. The applicant stated that a foot pedal connected to the user interface activates the main functions of the system so that the user's hands are free to perform the colonoscope procedure in a standard fashion.

The applicant stated that the evacuation mode (also referred to as suction) removes fecal matter and fluids out of the colon. The applicant noted that the evacuation function is active during cleansing so that fluid is inserted and removed from the colon simultaneously. The applicant explained that the evacuation pumps are designed in a manner that prevents the colon from collapsing when suctioning, which facilitates the ability to simultaneously irrigate and evacuate the colon. According to the applicant, during evacuation, the system continuously monitors the pressure in the evacuation channels of the oversleeve and if the pressure drops below pre-set limits the pumps will automatically reverse the flow. The applicant explained that the clog sensor triggers the system to automatically purge the material out of the channel and back into the colon where it can be further emulsified by the Pulsed Vortex Irrigation Jet, and then automatically reverts back into evacuation mode once the channel is cleared. The applicant stated that the evacuation (suction) that drains fecal matter and fluids out of the colon is generated by peristaltic pumps that can rotate in both directions, either to evacuate fluids and fecal matter from the colon through the evacuation tubes and into a waste container, or while in the reverse direction, to purge the evacuation tubes. The applicant claimed the suction created by this type of pump creates a constant volume draw of material from the colon and therefore prevents the colon from collapsing rapidly. According to the applicant, purging of evacuation tubes may be activated in two ways: The purging cycle is automatically activated when low pressure is noted by the evacuation-line sensor (it is also activated for the first 0.5 seconds when evacuation is activated to make sure the line is clear from the start); or a manual purge may be activated by the user by pushing the ''manual purge'' button on the foot pedal. The applicant claimed the pressure-sensing channel is kept patent by using an air perfusion mechanism where an electrical pump is used to perfuse air through the main connector and into the oversleeve, while the sensor located in the workstation calculates the pressure via sensing of the channel.

The applicant explained the Pure-Vu® System is loaded over a colonoscope and that the colonoscope with the Pure-Vu® Oversleeve is advanced through the colon in the same manner as a standard colonoscopy. The applicant stated that the body of the oversleeve consists of inner and outer sleeves with tubes intended for providing fluid path for the cleansing irrigation (2X), the evacuation of fluids (2X), the evacuation sensor (1X) and that the flexible head is at the distal end of the oversleeve and is designed to align with the colonoscope's distal end in a consistent orientation. The applicant explained that the distal cleansing and evacuation head contains the irrigation ports, evacuation openings, and a sensing port. According to the applicant, the system gives the physician the control to cleanse the colon as needed based on visual feedback from the colonoscope to make sure they have an unobstructed view of the colon mucosa to detect and treat any pathology. The applicant noted that since the Pure-Vu® System does not interfere with the working channel of the colonoscope, the physician is able to perform all diagnostic or therapeutic interventions in a standard fashion with an unobstructed field of view.

With respect to the newness criterion at § 419.66(b)(1), the Pure-Vu® System first received FDA 510(k) clearance on September 22, 2016 under 510(k) number K60015. Per the applicant, this initial device was very cumbersome to set up and required direct support from the company and therefore was not viable for a small company with limited resources to market the device. The applicant noted that the initial device could have been sold starting on January 27, 2017 when the first device came off the manufacturing line. Per the applicant, the device was allocated for clinical evaluations but 10 institutions throughout the country did purchase the device outside of any true clinical study, mostly based on the fact that

physicians wanted to try the product prior to committing to a clinical trial. The applicant further noted that minor modifications were made to the Pure-Vu® System in additional 510(k) clearances dated December 12, 2017 and June 21, 2018. The current marketed Pure-Vu® System was then granted 510(k) clearance on June 6, 2019 under 510(k) number K191220. Per the applicant, this clearance changed the entire set-up of the device, redesigned the user interface, and reduced the size, among other changes. According to the applicant, this updated version was commercially available as of September 19, 2019.

Comment: In response to CMS' summary, the applicant stated that the Pure-Vu® System Generation 1 (Gen 1) received FDA 510(k) clearance in September 2016. The applicant added that the Gen 1 version of the system was used to gather clinical data using disposables sold at a discounted rate to one institution and five institutions in 2017 and 2018, respectively. According to the applicant, after receiving feedback from providers concerning the Gen 1 system, the company decided not to make the Gen 1 product available to the market. According to the applicant, the Generation 2 (Gen 2) version of the Pure-Vu® System obtained FDA 510(k) clearance in June 2019. The applicant clarified that no application for the Gen 1 device was submitted for pass-through payment in the outpatient setting and asserted that since only a few institutions purchased the device, the cost burden of the Gen 1 system is not factored into the current marketplace. The applicant stated that the Gen 2 version is the product for which the applicant is seeking transitional device pass-through status.

Response: We appreciate the commenter's input and agree that the Pure-Vu® System meets the newness criterion because we received its device pass-through application on September 1, 2020, which is within 3 years of the June 21, 2018, the date of FDA PMA.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Pure-Vu® is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted temporarily. The applicant also claimed that Pure-Vu® meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We invited public comments on whether Pure-Vu® meets the eligibility criteria at § 419.66(b).

We did not receive any comments on whether Pure-Vu® meets the eligibility criteria at § 419.66(b)(3) or § 419.66(b)(4). We agree with the applicant that Pure-Vu® device meets the criteria of § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We stated in the CY 2022 OPPS/ASC proposed rule that we have not identified an existing pass-through payment category that describes Pure-Vu®. We invited public comment on whether Pure-Vu® meets the device category criterion.

We did not receive any comments on whether Pure-Vu® meets the eligibility criteria at § 419.66(c)(1). We continue to believe that Pure-Vu® device meets the criteria of § 419.66(c)(1) because we have not identified an existing pass-through payment category that describes Pure-Vu®.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. The applicant stated that Pure-Vu® represents a substantial clinical improvement over existing technologies. With respect to this criterion, the applicant submitted studies that examined the impact of Pure-Vu® on endoscopic hemostasis outcomes, rebleeding occurrence, and mortality. We note that the applicant has applied for and was denied the New Technology Add-on Payment in the FY 2022 IPPS/LTCH proposed rule (86 FR 25299 through 25304).

According to the applicant, the Pure-Vu® System offers the ability to achieve rapid beneficial resolution of the disease process treatment by achieving rapid and full visualization of the colon, which will improve diagnostic yield and the effectiveness of treatment of diseases of the bowel. The applicant claimed that Pure-Vu® is indicated for use in emergent issues such as acute lower gastrointestinal (GI) bleeding, unknown abdominal pain, foreign body removal, chronic disease management, and preventive medicine such as screening and surveillance. The applicant states these procedures are typically performed using a colonoscope to visualize the colon and provide a conduit to deliver therapeutic treatments. According to the applicant, the current standard of care requires the colon to be cleansed to ensure the success of any procedure. The applicant asserts that in the case where pre-procedural preparations are not adequate to achieve proper visualization, current technology provides limited ability to remove debris from the colon during the procedure to facilitate the process. The applicant states that regardless of indication, the bowel preparation remains the constant across patients who may have a wide range of comorbidities which may limit patient tolerability. According to the applicant the consumption of a purgative and the dietary restriction to be on clear liquids for approximately 24 hours can be problematic for the diabetic and elderly populations.[156]

In support of its application, the applicant submitted three outpatient clinical studies to demonstrate the Pure-Vu® System's capability to convert patients to adequate preparation where preparation was previously inadequate and the visualization was poor based on the Boston Bowel Preparation Scale (BBPS). In the first study, Perez J., et al. conducted an outpatient prospective pilot study using the Pure-Vu® System.[157] The study observed 50 patients with poorly prepared colons undergoing colonoscopy at two outpatient clinical sites in Spain and Israel, respectively. The applicant claimed study patients underwent a reduced bowel preparation consisting of the following: No dried fruits, seeds, or nuts starting 2 days before the colonoscopy, a clear liquid diet starting 18 to 24 hours before colonoscopy, and a split dose of 20mg oral bisacodyl. The study found the number of patients with

[156] Parra-Blanco A, Ruiz A, Alvarez-Lobos M, Amoros A, Gana JC, Ibanez P, et al. Achieving the best bowel preparation for colonoscopy. World J Gastroenterol. 2014;20(47):17709- 26.

[157] Perez Jimenez J, Diego Bermudez L, Gralnek IM, Martin Herrera L, Libes M. An Intraprocedural Endoscopic Cleansing Device for Achieving Adequate Colon Preparation in Poorly Prepped Patients. J Clin Gastroenterol. 2019;53(7):530–4.

an adequate cleansing level (BBPS≥2 in each colon segment) increased significantly from 31 percent (15/49) prior to use of the Pure-Vu System (baseline) to 98 percent (48/49) after use of the Pure-Vu® System ($P < 0.001$), with no serious adverse events reported.

In the second study provided by the applicant, van Keulen, et al. also conducted a single-arm, prospective study on 47 patients with a median age of 61 years in the outpatient setting in the Netherlands using the Pure-Vu® System.[158] Within the study, cecal intubation was achieved in 46/47 patients. This multicenter feasibility study found that the Pure-Vu® System significantly improved the proportion of patients with adequate bowel cleansing from 19.1 percent prior to the use of the Pure-Vu® System to 97.9 percent after its use ($P < 0.001$) and median BBPS score (from 3.0 [IQR 0.0–5.0] to 9.0 [IQR 8.0–9.0]).

In the third study provided by the applicant that directly evaluated the Pure-Vu® System in a clinical setting, Bertiger G., *et al.* performed a United States-based single center, prospective, outpatient study investigating regimes of reduced outpatient bowel preparations, which included low doses of over-the-counter laxatives, and eliminating the typical 24 hour clear liquid diet restriction, which was replaced by a low residue diet the day before the procedure.[159] In this study, 46 of a possible 49 patients received a colonoscopy, 8 of which took the over-the-counter laxative (''MiraLAX arm''), 21 patients ingested two doses of 7.5oz Magnesium Citrate (MgC) each taken with 19.5oz of clear liquid (''Mag Citrate 15oz arm''), and 18 patients ingested 2 doses of 5oz MgC taken with 16oz of clear liquid (''Mag Citrate 10oz arm''). Of the 46 subjects, 59 percent were males and there was a mean age of 61±9.48 years. The study found that each of the 3 study arms revealed significant differences in BBPS score between the baseline preparation and post-cleansing via Pure-Vu®. All the preparation regimens resulted in inadequately prepped colons. Comparing the mean BBPS rating for both pre- and post- Pure-Vu® use, the MiraLAX arm was inferior ($P < 0.05$) to both Mag Citrate arms. For the MiraLAX arm, the mean BBPS Score improved from 1.50 to 8.63. For the Mag Citrate 15oz arm, the mean BBPS score improved from 3.62 to 8.95. For the Mag Citrate 10oz arm, the mean BBPS Score improved from 4.76 to 9.0.

The applicant also provided a self-sponsored, U.S.-based, multicenter, prospective, single arm study in the inpatient setting, analyzing 94 patients, 65 of which (68 percent) had a GI bleed.[160] Of the 94 patients (41 percent females/59 percent males), the mean age was 62 years. According to the applicant, the study's primary endpoint was the rate of improved bowel cleansing level from baseline to after use of the Pure-Vu® System per colon segment using the BBPS. The BBPS score was recorded for each colorectal segment (left colon, transverse colon, and right colon segments) both prior to (baseline) and after colon cleansing with the Pure-Vu® System. An adequate cleansing level was *a priori* defined as a BBPS ≥2 in all evaluated colon segments. The study found that in 79 of the 94 patients (84 percent), the physician was able to successfully diagnose or rule out a GI bleed in the colon per the patients' colonoscopy indication using only the Pure-Vu® System. The analysis showed statistically significant visualization improvement in each colon segment after Pure-Vu® use with a mean BBPS score in the descending colon, sigmoid, and rectum of 1.74 pre-Pure-Vu® use and 2.89 post-Pure-Vu® use ($P < 0.001$); in the transverse colon of 1.74 pre-Pure-Vu® use and 2.91 post Pure-Vu® use ($P < 0.001$); and the ascending colon and cecum of 1.50 pre-Pure-Vu® use and 2.86 post Pure-Vu® use ($P < 0.001$). The study found only 2 percent of cases where the diagnosis could not be achieved due to inadequate preparation. Overall, the 84 (89.4 percent) patients that received the Pure-Vu® System within the study improved BBPS scores from 38 percent (95 percent CI 28, 49) to 96 percent (95 percent CI 90, 99) in segments evaluated. The study noted one procedure related perforation which required surgical repair, and the patient was discharged 48 hours post operatively and recovered fully.

In addition to the previously discussed studies, the applicant also submitted two case studies to highlight the various clinical presentations of lower gastrointestinal bleed (LGIB) with the use of the Pure-Vu® System. In the first case, the applicant described a patient with a history of scleroderma and chronic constipation who was referred for a surveillance colonoscopy after a prior endoscopic mucosal resection due to a large polyp. The applicant states this was the patient's third colonoscopy in twelve months due to a history of poor preparation in the prior exams. Despite an aggressive prep regime, the applicant states the patient still had solid stool and debris throughout the colon. The applicant states the Pure-Vu® system was used extensively and the physician was able to fully cleanse the colon during which the physician was able to uncover a poorly defined over 1 cm sessile serrated polyp that could not be appreciated before cleansing with Pure-Vu®. The applicant states a successful polypectomy was performed.

In the second case, the applicant described a patient presenting with hemorrhagic shock and acute kidney injury six days after a colonoscopy where nine polyps were removed, including two polyps greater than 2 cm. The applicant states angiographic control of the bleeding was not considered because of the patient's acute kidney injury with a rising creatinine. According to the applicant, the physician elected to use Pure-Vu® to immediately exam the patient without any preparation doing a bedside colonoscopy in the ICU. The applicant states, the physician was able to cleanse the colon, locate the source of the bleed and create hemostasis by placing two clips on the bleed. According to the applicant, the entire colon was visualized to confirm there were no other sources of bleeding, the physician was able to downgrade the patient out of the ICU that same day, and the patient was discharged from the hospital the following day.

The applicant concludes that based on the provided evidence, Pure-Vu® has the ability to improve adenoma detection rates which can reduce the rate of colorectal cancer (CRC) and diagnose and treat emergent patients in a more expeditious fashion by removing the need to have successful pre-procedural preparation that can take time and be very burdensome to the most needy and fragile patients. According to the applicant, Pure-Vu® can minimize the number of aborted and early repeat colonoscopies that carry inherent risks and add unnecessary costs to the healthcare system.

Based on the evidence submitted with the application, we explained in the CY 2022 OPPS/ASC proposed rule that we have the following observations. While

[158] Van Keulen KE, Neumann H, Schattenberg JM, Van Esch AAJ, Kievit W, Spaander MCW, Siersema PD. A novel device for intracolonoscopy cleansing of inadequately prepared colonoscopy patients: A feasibility study. Endoscopy. 2019 Jan;51(1):85–92. doi: 10.1055/a–0632–1927. Epub 2018 Jul 11.

[159] Bertiger, Gerald MD Optimizing the Preparation Regimen Prior to Colonoscopy Procedure With the Pure-Vu® System, American Journal of Gastroenterology: October 2018—Volume 113—Issue—p S119–S120.

[160] Helmut Neumann ML, Tim Zimmermann, Gabriel Lang, Jason B. Samarasena, Seth A. Gross, Bhaumik Brahmbhatt, Haleh Pazwash, Vladimir Kushnir. Evaluation of bowel cleansing efficacy in hospitalized patient population using the pure-vu system. Gastrointestinal Endoscopy. 2019;89(6).

the studies provided in support of the Pure-Vu® System measure improvement of bowel preparation using the BBPS, the applicant did not provide data indicating that the improved BBPS directly leads to improved clinical outcomes (for example, reduction of blood loss in LGIB or reduction of missed polyps) based on use of the Pure-Vu® System. Additionally, we noted that the applicant has not provided any studies comparing the efficacy of the Pure-Vu® System to other existing methods or products for irrigation in support of its claims that the product is superior at removing debris from the colon while simultaneously preventing the colon from collapsing, allowing use of the working channel, or improving outcomes. Furthermore, we noted that many of the provided studies were based on small sample sizes, which may affect the quality and reliability of the data provided in support of the technology.

In addition, we noted in the CY 2022 OPPS/ASC proposed rule that it is unclear whether this device would have less utility in the outpatient setting as compared to the inpatient setting, given that patients will typically have time to adequately prepare for scheduled outpatient procedures. We further noted that this device may not be broadly applicable in the outpatient setting and are solicited comment on situations in which this device would have a substantial clinical benefit for patients or subpopulations of patients. For instance, in the outpatient setting, we explained that we are not certain that it would be appropriate to use this device in the case of a patient with a poorly prepared bowel as opposed to simply rescheduling the appointment.

Lastly, we noted that the Helmut *et al.* study noted one procedure-related perforation which required surgical repair and we invited public comments regarding the concern of procedure-related perforation.[161] Based upon the evidence presented, we invited public comments on whether the Pure-Vu® meets the substantial clinical improvement criterion.

Comment: One commenter stated that Pure-Vu® is a unique device with the ability to potentially change a patient's course of care due to its ability to create high-quality colonoscopies in patients that are unable to fully prep for an exam. The commenter stated that they want to make sure that patients who suffer from functional GI and motility disorders which affect the lower GI tract can get the surveillance and care that they need and Pure-Vu® can directly impact this. The commenter asserted there is a direct correlation between being able to provide a high-quality colonoscopy where the more the colon mucosa can be observed and the ability to better diagnose patients.

Response: We appreciate the information provided by the commenter and have taken this into consideration in making our final determination, discussed below.

Comment: In support of the substantial clinical improvement criterion, the applicant submitted a comment. The applicant responded to CMS' concerns in the proposed rule related to the Boston Bowel Preparation Score (BBPS) and stated that this is a measure of the amount of the colon mucosa that can be visualized and is independent of a particular technology or method used to clear fecal matter or debris. The applicant asserted that if significant areas of the colon tissue cannot be visualized due to retained debris, the endoscopist will miss any pathology covered. The applicant stated that this is especially critical as sessile serrated adenomas are pre-cancerous flat lesions that do not protrude from the colon wall making them impossible to detect in the presence of debris. According to the applicant, multiple publications validating the BBPS as a reliable measurement to predict adenoma and/or polyps have been published, for example: The polyp detection percentage in inadequate (BBPS 0, 1) and adequate (BBPS 2, 3) colon prep were 6 percent and 27 percent ($p < 0.0001$), respectively and,[162] the polyp detection rate was 40 percent for patients with a BBPS score >5 compared to 24 percent for patients with a BBPS score of <5 ($p < 0.02$) with an increased percentage of recommendation for repeat procedures in the later group.[163] The applicant further described the Aronchick scale and the Ottawa score which are other validated methods available to assess colon visualization.[164] According to the applicant, these cited studies were based on current standard of care for performing colonoscopy. The applicant stated that despite use of the current standard of irrigation and suction through the working channel of a colonoscope, these patients continued to have inadequate bowel preparation over 7 percent. The applicant asserted that to the extent there is a reduction in the number of patients that have an inadequate/poor preparation, as noted by a low BBPS score, the endoscopist will improve the overall adenoma detection rate.

According to the applicant, there is a clear relationship between adenoma detection rates to the risk of receiving a diagnosis of an interval cancer as evidenced in an evaluation of 314,872 patients.[165] Citing the article, the applicant states that, ''The risk of interval cancer decreased approximately linearly with increasing adenoma detection rates, without evidence of a threshold effect within the observed range of rates. With adenoma detection rate modeled as a continuous variable, each 1.0 percent increase in the rate predicted a 3.0 percent decrease in the risk of interval cancer (hazard ration, 0.97;95 percent CI, 0.96 to 0.98).'' [166] According to the applicant, this study shows the clinical benefit to the patient population with low adenoma detection rates due to inadequate preparation, especially in high risk colorectal cancer patients who present with GI bleeding or a positive screening test, may be significant.

The applicant next responded to CMS' concerns about the sample sizes from the studies used in support of Pure-Vu®. In response, the applicant performed a meta-analysis of the four studies which were performed at different centers with different investigators to minimize the bias of any physician or institution. According to the applicant, for outpatient studies, the overall rate of adequate colonoscopy preparation was 99.4 percent compared to 25.3 percent for baseline; and the overall difference was 74.1 percent (95 percent CI = 60.3 percent, 87.8 percent; $p < 0.0001$); the inpatient study had a lower overall success rate in the Pure-Vu® System (86.2 percent) but the impact of the Pure-Vu® was still dramatic with the overall rate of adequate colonoscopy preparation of 95.0 percent compared to 28.2 percent

[161] Helmut Neumann ML, Tim Zimmermann, Gabriel Lang, Jason B. Samarasena, Seth A. Gross, Bhaumik Brahmbhatt, Haleh Pazwash, Vladimir Kushnir. EVALUATION OF BOWEL CLEANSING EFFICACY IN HOSPITALIZED PATIENT POPULATION USING THE PURE–VU SYSTEM. Gastrointestinal Endoscopy. 2019;89(6).

[162] Kluge MA, Williams JL, Wu CK, et al. Inadequate Boston Bowel Preparation Scale scores predict the risk of missed neoplasia on the next colonoscopy. Gastrointest Endosc. 2018 Mar;87(3):744–751.

[163] Lai EJ, Calderwood AH, Doros G, et al. The Boston bowel preparation scale: a valid and reliable instrument for colonoscopy-oriented research. Gastrointest Endosc. 2009 Mar;69(3 Pt 2):620–5.

[164] Hong SN, Sung IK, Kim JH, et al. The Effect of the Bowel Preparation Status on the Risk of Missing Polyp and Adenoma during Screening Colonoscopy: A Tandem Colonoscopic Study. Clin Endosc. 2012 Nov;45(4):404–11.

[165] Corley DA, Jensen CD, Marks AR, et al. Adenoma detection rate and risk of colorectal cancer and death. N Engl J Med. 2014 Apr 3;370(14):1298–1306.

[166] Ibid.

for baseline; and the overall difference was 66.8 percent (95 percent CI = 55.5 percent, 78.0 percent; $p < 0.0001$).

Next the applicant responded to CMS' concern that the benefit of Pure-Vu® in the outpatient setting may be limited because patients have more time to prepare for the colonoscopy. According to the applicant, there are many patients that the physician may pre-procedurally deem ready for the examination but upon insertion of the colonoscope the patient is found to be inadequately prepared to receive a quality examination. The applicant stated that, rather than terminate the procedure at this point, an endoscopist can remove the colonoscope and load the Pure-Vu® and complete the examination. The applicant added that in the studies used in the meta-analysis, Pure-Vu® was able to convert inadequate preparation to adequate even in patients with a BBPS of 0 in one or more segments of the colon while the patient was on the table and under sedation, thereby avoiding another procedure. The applicant asserted that in addition to the risks associated with a repeat procedure, approximately 54 percent of patients do not come back for the repeat examination which places these patients at a higher risk for CRC.[167] The applicant added that since history of inadequate preparation is one of the main indicators of poor preparation along with advanced age, those with motility issues, patients allergic to the PEG (key ingredient in the purgatives) and those with comorbidities there is no guarantee the follow-up colonoscopy will be successful.

Next the applicant addressed CMS' concern that there was no data to support that Pure-Vu® minimizes the colon collapsing during suctioning of debris while allowing use of the working channel of the scope. The applicant asserted that the provision of a pulsed mixture of air and fluid to break up and facilitate removal of adherent films of fecal matter from the mucosal lining of the colon, at a much higher energy level than irrigation through a scope, allows the endoscopist to simultaneously suction the debris, which is not possible through a scope with only one working channel. The applicant stated, the simultaneous action of pumping water and air into the colon while suctioning out debris inherently reduces the likelihood that the colon will collapse.

Lastly, in response to CMS' concern related to one procedure-related perforation, the applicant stated that this study focused on the inpatient population which is known to be at higher risk for perforation than the outpatient population.[168] The applicant stated that this patient was discharged 48 hours post operatively and fully recovered with no additional clinical sequelae. The applicant asserted that inpatient cases undergoing colonoscopy are a high risk for perforation with a rate of approximately 1 in 500, which is more than two times higher than the outpatient population.[169] The applicant stated that since the Helmut paper they have developed the Gen 2 Pure-Vu® and have received no adverse reports in the last 18 months even with increased utilization across multiple institutions.

Response: We appreciate the comment in support of the clinical benefits of the Pure-Vu® system. As we stated in the FY 2022 IPPS/LTCH final rule (86 FR 45056), we continue to have concerns regarding the substantial clinical improvement criterion. In response to commenters' assertion that there is a direct correlation to being able to provide high-quality colonoscopy where the more the colon mucosa can be observed and the ability to better diagnose patients, we agree but are aware that correlation is not causation. While these data are correlated, without data testing this relationship (for example, the Pure-Vu® system and patient outcomes such as adenoma detection rates), we cannot be certain this relationship is true and not spurious or mediated by other factors. We note the further input provided by the applicant concerning the validity of the BBPS and agree that this is likely a well validated scoring tool. However, we remain concerned that the studies provided in support of the Pure-Vu® System measure improvement of bowel preparation using the BBPS but do not provide data indicating that the improved BBPS directly leads to improved clinical outcomes. In addition, the studies did not demonstrate outcomes in the emergent situations the Pure-Vu® System is intended to address. While an additional study provided by the applicant in their comment indicated a general link between improved BBPS and advanced adenoma detection rates, we note that the study occurred in patients undergoing screening colonoscopy, and did not include the use of the Pure-Vu® system. We also remain concerned about the lack of studies comparing the Pure-Vu® System to other existing methods or products for irrigation in support of its claims that the product is superior at removing debris from the colon while simultaneously preventing the colon from collapsing, allowing use of the working channel, or improving outcomes.

After consideration of the public comments we received and our review of the device pass-through application, we are not approving the Pure-Vu® system for transitional pass-through payment status in CY 2022 because the product does not meet the substantial clinical improvement criterion. Because we have determined that the Pure-Vu® system does not meet the substantial clinical improvement criterion, we are not evaluating whether the device meets the cost criterion.

(6) Xenoscope™

Xenocor Inc. submitted an application for a new device category for transitional pass-through payment status for the Articulating Xenoscope Laparoscope (hereinafter referred to as the Xenoscope™) by the March 2021 quarterly deadline for CY 2022. The applicant described the Xenoscope™ as a disposable laparoscope which consists of a high-definition camera chip on the tip of a composite shaft, paired with led lights with a handle comprised of a clamshell design and made with molded plastic. The applicant stated that the Xenoscope™ provides visualization in the abdominal and thoracic cavities through small, minimally invasive incisions for diagnostic and therapeutic laparoscopic procedures in a similar fashion to established, reusable versions of laparoscopes. It is paired with an image processing unit, the Xenobox, that can plug into any HD monitor to display anatomy in the abdomen, pelvis or chest. The Xenobox uses pre-installed firmware that is upgradable.

The applicant claimed that the Xenoscope™ is the first disposable laparoscope. The applicant also claimed that the use of the Xenoscope™ reduces the number of cords in the operating room, eliminates intraoperative fogging and associated image compromise and eliminates up-front capital expenditures associated with reusable laparoscopes.

With respect to the newness criterion, the Xenoscope™ received FDA 510(k) clearance on January 27, 2020, based on

[167] Murphy CJ, Jewel Samadder N, Cox K, *et al.* Outcomes of Next-Day Versus Non-next-Day Colonoscopy After an Initial Inadequate Bowel Preparation. Dig Dis Sci. 2016 Jan;61(1):46–52.

[168] Helmut Neumann ML, Tim Zimmermann, Gabriel Lang, Jason B. Samarasena, Seth A. Gross, Bhaumik Brahmbhatt, Haleh Pazwash, Vladimir Kushnir. EVALUATION OF BOWEL CLEANSING EFFICACY IN HOSPITALIZED PATIENT POPULATION USING THE PURE–VU SYSTEM. Gastrointestinal Endoscopy. 2019;89(6).

[169] Gatto NM, Frucht H, Sundararajan V, *et al.* Risk of perforation after colonoscopy and sigmoidoscopy: a population-based study. J Natl Cancer Inst. 2003 Feb 5;95(3):230–6.

a determination of substantial equivalence to a legally marketed predicate device. The Xenoscope™ is indicated for use in diagnostic and therapeutic procedures for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs. We received the application for a new device category for transitional pass-through payment status for the Xenoscope™ on August 6, 2020, which is within 3 years of the date of the initial FDA marketing authorization. We invited public comments in the CY 2022 OPPS/ASC proposed rule on whether the Xenoscope™ meets the newness criterion.

We did not receive any comments with respect to the newness criterion.

We agree with the applicant that the Xenoscope™ meets the newness criterion because we received its device pass-through application on August 6, 2020, which is within 3 years of January 27, 2020, the date of FDA 510(k) clearance.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of the Xenoscope™ is integral to the service, is used for one patient only, comes in contact with human skin, and is surgically implanted or inserted into the patient. Specifically, the applicant explained that the Xenoscope™ is plugged into the Xenobox image processing unit (which is connected to an HD monitor and an A/C power source). A surgeon then makes a small incision and a trocar (tube-like device with a seal to maintain abdominal pressure) is inserted to gain access to the body cavity. The Xenoscope™ is then inserted through the trocar in order to provide a full view of the anatomy for diagnostic and therapeutic procedures.

The applicant also claimed the Xenoscope™ meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We invited public comments on whether the Xenoscope™ meets the eligibility criteria at § 419.66(b).

We did not receive any comments in regard to the eligibility criteria at § 419.66(b). We agree with the applicant and believe that the Xenoscope™ meets the eligibility criterion at § 419.66(b)(3) and (4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant described the Xenoscope™ as disposable laparoscope. The applicant reported that it does not believe that the Xenoscope™ is described by an existing category and requested category descriptor ''Single-use laparoscopes.'' The applicant also stated that the currently existing category, C1748—Endoscope, single-use (that is, disposable), upper gi, imaging/illumination device (insertable), did not describe this device because it is limited to single-use duodenoscopes inserted orally, to reach the small intestine versus minimally invasive abdominal surgery (laparoscopy). We stated in the CY 2022 OPPS/ASC proposed rule that we have not identified an existing pass-through payment category that is applicable to the Xenoscope™. We invited public comment on whether the Xenoscope™ meets the device category criterion.

We did not receive any comments in regard to the eligibility criteria at § 419.66(c). We continue to believe that the Xenoscope™ meets the eligibility criterion at § 419.66(c)(1) because we have not identified an existing pass-through payment category that is applicable to the Xenoscope™.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization.

With respect to the substantial clinical improvement criterion, the applicant stated that the Xenoscope™ provides a substantial clinical improvement over reusable laparoscopes because of its single-use nature. Specifically, the applicant claimed that because the Xenoscope™ is a disposable, single-use device, the Xenoscope™ provides for less risk of scope-related cross-contamination and infection from improperly handled or reprocessed scopes compared to traditional laparoscopy.

The applicant also claimed that the Xenoscope™ includes a fog-free scope and provides a substantial clinical improvement over currently available laparoscopes which, according to the applicant, fog often, and can put patients at risk for surgical errors and more time under anesthesia. Additionally, the applicant claimed that the Xenoscope™ reaches 104 degrees Fahrenheit at the tip, eliminating risk of patient burns and drape fires associated with hotter Xenon bulbs used in currently available laparoscopes.

Lastly, that applicant stated that there can be significant economic benefits through the use of the Xenoscope™ due to the processing costs and up-front capital expenditures required for reusable laparoscopes.

In support of the assertion that the Xenoscope™ reduces the risk of cross-contamination from improperly cleaned reusable laparoscopic instruments, the applicant referenced two articles. The first article was published in 2002 and describes the problem of surgical site infection (SSI), the Centers for Disease Control (CDC) guidelines for SSI, and some cases of SSI related to improper cleaning of reusable laparoscopic instruments. The article also discusses practices to avoid these infections.[170] The applicant also submitted a draft of a manuscript titled ''Novel Laparoscopic System for Quality Improvement and Increased Efficiency'' that summarizes some of the evidence that laparoscopy, in general, is superior to open surgical approaches in terms of pain management and infection risk.[171]

In support of the claim that the Xenoscope™ eliminates the risk of patient burns and drape fires associated with Xenon bulbs used by currently available laparoscopes, the applicant submitted two articles. The first was an article published in 2011 that discusses the problem of laparoscopic related burn injuries and a potential solution using Active Electrode Monitoring (AEM).[172] AEM instruments reportedly use a ''shielded and monitored'' design to prevent the risk of stray energy burn injury from insulation failure and capacitive coupling. According to the article, the AEM technology is currently

[170] Hewitt, A. (2002, November 1). *Laparoscopic Instruments: Handle with Care.* Infection Control Today. *https://www.infectioncontroltoday.com/view/laparoscopic-instruments-handle-care.*

[171] Elliott, K.W. & Heilbraun, E. (2020). *Novel Laparoscopic System for Quality Improvement and Increased Efficiency.* Manuscript submitted for publication.

[172] Encision Inc. (2011, April 1*). Method of Reducing Stray Energy Burns in Laparoscopic Surgery.* Medical Design Briefs. *https://www.medicaldesignbriefs.com/component/content/article/mdb/tech-briefs/9500.*

licensed by Intuitive Surgical's da Vinci® Surgical Systems. The applicant does not compare the Xenoscope™ to AEM technology in terms of burn injury reduction. The second article examined the variation and extent of thermal injuries that could be induced by laparoscopic light sources to porcine tissue. In the study, the maximum temperature at the tip of the optical cable varied between 119.5 degrees C and 268.6 degrees C. When surgical drapes were exposed to the tip of the light source, the time to char was 3–6 seconds. The degree and volume of injury increased with longer exposure times, and significant injury was recorded with the optical cable 3 mm from the skin.[173]

In support of the claim that there could be significant economic benefits realized through the use the Xenoscope™ compared to reusable laparoscopes, the applicant also referenced the manuscript entitled ''Novel Laparoscopic System for Quality Improvement and Increased Efficiency''.[174] In this study, a three-page survey was created to collect data regarding laparoscope-related practices and costs. The survey was completed by three different institutions, including an ambulatory surgery center (ASC), a rural hospital and a suburban hospital. The sites provided the capital equipment cost required at the time of purchase at their facility which ranged from $837,184 to $2,786,348. The average cost per use for one surgical procedure involving a reusable laparoscope was $1,019.24 across the three institutions.

We stated in the CY 2022 OPPS/ASC proposed rule that we are concerned that the application and the articles submitted as evidence of substantial clinical improvement discuss potential adverse effects from laparoscopic procedures, but do not appear to directly show any clinical improvement that result from the use of the Xenoscope™. The applicant has provided evidence which seems to rely on indirect inferences from other sources of data. The articles provided did not involve the clinical use of the Xenoscope™ and did not compare the device to an appropriate comparator, such as a reusable laparoscope. Therefore, we stated that it is difficult to determine whether the Xenoscope™ offers substantial clinical improvement over standard, reusable laparoscopes based on the information provided. In order to demonstrate substantial clinical improvement over currently available treatments, we consider supporting evidence, preferably published peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care.

We invited public comment on whether the Xenoscope™ meets the substantial clinical improvement criterion.

Comment: One commenter stated their opposition to the use of HCPCS code 58570 (Tlh uterus 250 g or less) in conjunction with the Xenoscope™. The commenter stated that multiple searches in PubMed did not produce evidence of use or clinical improvement for gynecologic laparoscopic procedures, including HCPCS code 58570 (Tlh uterus 250 g or less). The commenter asserted that Obstetrician-gynecologists and gynecologic oncologists are the primary billers of 58570 and employ laparoscopy for many other surgeries such as tubal ligation and hysterectomy, positioning them as potential high-utilizers of new devices such as the Xenoscope™. The commenter stated their concern for the unintended consequences of promoting the payment of a device for which a substantial clinical improvement in gynecologic surgery is undetermined.[175]

Response: We appreciate the input from the commenter and we have noted the lack of data demonstrating evidence of use or clinical improvement for gynecologic laparoscopic procedures. We refer the commenter to our final response and determination regarding the substantial clinical improvement criterion below for a discussion of this concern. However, we note that the indication for use as stated by the FDA in the 510(k) clearance letter is, ''The Articulating Xenoscope™ is intended to be used in diagnostic and therapeutic procedures for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs.'' Given the role of the FDA in defining device indications, we believe the device is appropriately described by HCPCS 58570.

Comment: A commenter representing Xenocor, Inc. stated that the safety profile for patients could be improved in the following ways: (1) Cross-contamination for the Xenoscope™ is not possible; (2) the Xenoscope™ has a top temperature of 129 degrees Fahrenheit where one of the most frequent causes of operating room fires and burns are traditional, reusable laparoscopes which often exceed 350 degrees Fahrenheit; (3) the Xenoscope™'s composite shaft is non-conductive which avoids risks with traditional laparoscopes which can arc stray current when using monopolar electrocautery where the scope acts as an antenna and burns adjacent structures; and (4) the Xenoscope™ eliminates fog and sees better through smoke and steam than any currently marketed resuables.

We also received multiple comments stating general support for the Xenoscope™. Two of the commenters stated that the Xenoscope™ reaches a temperature of 129 °F, as opposed to the 350 °F reached by light cords which can cause burns or patient injury, is fully shielded and will not cause stray energy burns or arcing issues that exist with other like products, its single-use nature ensures complete sterility and consistent image quality due to the new out of the box feature with each use, and the fog-free picture helps to ensure a consistent clear visualization of critical anatomy.

One commenter stated the benefits of the Xenoscope™ are critical to both patient safety and cost control. Another commenter stated that having a disposable scope would enable surgery to be done more easily in a wider variety of places while also eliminating many problems associated with traditional scopes. Another commenter added that the ability to use Xenoscope™ with any USB enabled video device obviates the need for expensive auxiliary light sources, video drivers, etc.

Response: We thank the commenters for their input. We agree that improved patient safety and a reduction in complications are clinical outcomes that may represent a substantial clinical improvement. However, we remain concerned that we did not receive any data to demonstrate improved outcomes using the Xenoscope™. Further, we remain concerned that the applicant did not provide any comparison to existing technologies such as reusable scopes to demonstrate an improvement in clinical outcomes. Lastly, we note that the cost effectiveness of a technology does not substantially improve the diagnosis or treatment of a disease and therefore is not relevant to the discussion of substantial clinical improvement.

[173] Hindle, A.K., Brody, F., Hopkins, V., Rosales, G., Gonzalez, F., & Schwartz, A. (2009). Thermal injury secondary to laparoscopic fiber-optic cables. *Surgical endoscopy, 23*(8), 1720–1723. *https://doi.org/10.1007/s00464-008-0219-z.*

[174] Ibid.

[175] Choosing the route of hysterectomy for benign disease. Committee Opinion No. 701. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017:129:e155–9.

After consideration of the public comments we received and our review of the device pass-through application, we are not approving the Xenoscope™ for transitional pass-through payment status in CY 2022 because the product does not meet the substantial clinical improvement criterion. Because we have determined that the Xenoscope™ does not meet the substantial clinical improvement criterion, we are not evaluating whether the device meets the cost criterion.

B. Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive APCs and is discussed in detail in section IV.B. of the CY 2022 OPPS/ASC proposed rule (86 FR 42112 through 42114). A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422) and is discussed in detail in section IV.B.3 of the CY 2022 OPPS/ASC proposed rule (86 FR 42114). For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, under the device-intensive methodology we assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the three criteria listed below. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APC designations were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status for procedures without a significant device cost that are granted such status because of their APC assignment.

Under our existing policy, procedures that meet the criteria listed in section IV.B.1.b. of the CY 2022 OPPS/ASC proposed rule (86 FR 42112 through 42114) are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.B.3. and IV.B.4. of the CY 2022 OPPS/ASC proposed rule, respectively (86 FR 42114 thorough 42115).

b. Use of the Three Criteria To Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy—which includes the three criteria listed previously—to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Device-Intensive Procedure Policy for CY 2019 and Subsequent Years

As part of our effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard from stakeholders that the criteria excluded some procedures that stakeholders believed should qualify as device-intensive procedures. Specifically, we were persuaded by stakeholder arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of -device-intensive procedures was warranted, and made two modifications to the criteria for CY 2019 (83 FR 58948). First, we allowed procedures that involve surgically inserted or implanted single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We established this policy because we no longer believe that whether a device remains in the patient's body should

affect a procedure's designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device-intensive. We stated that we believe allowing these additional procedures to qualify for -device-intensive status will help ensure these procedures receive more appropriate payment in the ASC setting, which will help encourage the provision of these services in the ASC setting. In addition, we stated that this change would help to ensure that more procedures containing relatively high-cost devices are subject to the device edits, which leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for CY 2019 and subsequent years, we finalized that—device-intensive procedures will be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not either of the following:

(a) Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

(b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a device that did not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent was not calculated from claims data; instead, it was applied as a default until claims data were available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 58945 through 58946, respectively), in accordance with our policy stated previously to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation or insertion of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining—device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have little or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does

not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

As we indicated in the CY 2019 OPPS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, or electronically at *outpatientpps@cms.hhs.gov*. Additional information can be submitted prior to issuance of an OPPS/ASC proposed rule or as a public comment in response to an issued OPPS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

As discussed in section X.E of the CY 2022 OPPS/ASC proposed rule (86 FR 42188 through 42190), given our concerns regarding CY 2020 data as a result of the COVID–PHE, we proposed to use CY 2019 claims data to establish CY 2022 prospective rates. While we continue to believe CY 2019 represents the best full year of claims data for ratesetting, we believe our policy of temporarily assigning a higher offset percentage if warranted by additional information would provide a more accurate device offset percentage for certain procedures. Specifically, for procedures that were assigned device-intensive status, but were assigned a default device offset percentage of 31 percent or a device offset percentage based on claims from a clinically-similar code in the absence of CY 2019 claims data, we proposed to assign a device offset percentage for such procedures based on CY 2020 data if CY 2020 claims information is available. While we believe that CY 2019 claims data is a better basis for CY 2022 OPPS rates overall, because we have specifically noted that we would consider using more recent data than the data available for ratesetting in a given year to determine device offset percentages for services that do not have any claims data in the year used for ratesetting, we believe it would be consistent with this policy for us to use CY 2020 claims data to determine the device offset percentage for services that meet the above criteria.

For CY 2022, our proposal would assign device offset percentages using CY 2020 claims data to the following 11 procedures:

- 0266T (Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed));
- 0414T (Removal and replacement of permanent cardiac contractility modulation system pulse generator only);
- 0511T (Removal and reinsertion of sinus tarsi implant);
- 0587T (Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve);
- 0600T (Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous);
- 0614T (Removal and replacement of substernal implantable defibrillator pulse generator);
- 66987 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (for example, iris ansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation);
- 66988 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation);
- C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar);
- C9765 (Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed); and
- C9767 (Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed).

Comment: Many commenters supported our proposal to establish the CY 2022 device offset percentage using CY 2020 claims data for device-intensive procedures with no claims in the CY 2019 claims data. One commenter requested that we use CY 2020 claims where CY 2020 claims volume is greater than CY 2019 claims volume. Another commenter requested that we apply the greater of the device offset percentage when comparing CY 2019 claims with CY 2020 claims.

Response: We thank the commenters for their support. We are not accepting the recommendation to apply data from CY 2020 claims where CY 2020 claims volume is greater than CY 2019 claims volume or to apply the greater of the device offset percentage when comparing CY 2019 claims with CY 2020 claims. Specifically, as discussed in section X.E of this final rule with comment period, we continue to believe CY 2019 represents the best full year of claims data for ratesetting. Therefore, we believe our proposal provides a more accurate device offset percentage only for certain device-intensive procedures that had no claims data in CY 2019 and for which the device offset percentage would otherwise be based on the default percentage or a similar procedure code's device offset percentage. *Comment:* Many commenters requested that we set the device offset percentage for several new procedures using the predecessor code's device offset percentage based on CY 2019 claims data. These procedures include:

- The predecessor CPT code 0191T in assigning the device offset percentage for CPT code 66989 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (for example, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (for example, trabecular

meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more);

- The predecessor CPT code 0191T in assigning the device offset percentage for CPT code 66991 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification); with insertion of intraocular (for example, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more);
- The predecessor CPT code 0191T in assigning the device offset percentage for CPT code 0671T (Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more);
- The predecessor CPT code 0548T in assigning the device offset percentage for CPT code 53451 (Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance);
- The predecessor CPT code 0549T in assigning the device offset percentage for CPT code 53452 (Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance); and
- The predecessor HCPCS code C9752 in assigning the device offset percentage for CPT code 64628 (Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral).

Additionally, at the August 23, 2021 HOP Panel Meeting, a presenter requested that we use the predecessor CPT code 64568 in assigning the device offset percentage for CPT code 64582 (Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array). Based on the information presented at the meeting, the HOP Panel recommended we use CPT code 64568 to assign the device offset percentage for CPT code 64582.

Response: We agree with the commenters and the HOP Panel's recommendation. We note that we inadvertently did not apply the device offset percentage to several new HCPCS codes where claims data for a predecessor code was available. Therefore, we are revising the device offset percentage for these procedures for this final rule with comment period using CY 2019 claims data from these procedures' predecessor codes.

Comment: A number of commenters recommended we assign device-intensive status to CPT codes 0627T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level) and 0630T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with ct guidance, lumbar; each additional level (list separately in addition to code for primary procedure)).

Response: We appreciate the commenters' recommendation. As we stated in the CY 2022 OPPS/ASC proposed rule (86 FR 42113), we finalized, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that ''has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review.'' The products involved when reporting CPT code 0627T and 0630T that the commenter believed should necessitate a device intensive designation do not meet this requirement. Therefore, we are not accepting the commenters' recommendations and are not granting device-intensive status to these codes.

Comment: One commenter requested that we assign HCPCS code C9778 (Colpopexy, vaginal; minimally invasive extra-peritoneal approach (sacrospinous)) device-intensive status as this procedure meets our device-intensive criteria.

Response: After further review, we agree with the commenter that HCPCS code C9778 meets our criteria for device-intensive status. We are accepting the commenter's recommendation and assigning a default device offset percentage of 31 percent to HCPCS code C9778 for CY 2022.

Comment: One commenter recommended assigning CPT code 66179 (Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft) as device-intensive as the procedure's device offset percentage is 32.78 percent in Addendum P to the CY 2022 OPPS/ASC proposed rule, which exceeds our 30-percent threshold for device-intensive status.

Response: We have reviewed this procedure code with our medical officers and have determined that this procedure satisfies all of our device-intensive criteria. In particular, we agree with the commenter that this procedure involves an implantable single-use device and that the device meets the requirements for the procedure to receive device-intensive assignment.

Comment: Commenters requested that we assign device-intensive status to:

- CPT code 0499T (Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed);
- CPT code 58674 (Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency);
- CPT code 50590 (Lithotripsy, extracorporeal shock wave);
- CPT code 59200 (Insertion of cervical dilator (*e.g.,* laminaria, prostaglandin) (separate procedure));
- CPT code 66174 (Transluminal dilation of aqueous outflow canal; without retention of device or stent);
- CPT code 66175 (Transluminal dilation of aqueous outflow canal; with retention of device or stent);
- CPT code 93571 (Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (list separately in addition to code for primary procedure); and
- HCPCS code C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar).

Response: Based on CY 2019 claims data available for this final rule with comment period, the procedures requested by commenters do not have device offset percentages that exceed the 30-percent threshold required for device-intensive status and, therefore, are not eligible to be assigned device-intensive status under the OPPS.

Comment: Some commenters submitted invoices and requested a greater device offset amount and greater device offset percentage to reflect the invoice price of a particular device.

Other commenters also recommended utilizing invoice prices to establish device offset percentages for procedures with low or no claims volume or to correct situations commenters contend reflect underreported device costs attributable to hospital confusion when reporting HCPCS code C1889 (Implantable/insertable device, not otherwise classified).

Response: While we appreciate the recommendations and additional information submitted by commenters, we are not applying the invoice prices submitted by commenters to establish the device offset amount and device offset percentage for these procedures. None of the invoice prices that were submitted suggest that we should apply our policy of temporarily applying a higher device offset percentage if warranted by additional information. As we have stated in previous rulemaking (85 FR 86015), this policy of temporarily assigning a higher device offset percentage should be applied in rare instances, such as using CY 2020 claims data in light of the COVID–19 PHE or where a device has an extremely abnormal cost and, in the absence of claims data, may be significantly underpaid under our policy to apply a default device offset percentage for the procedure that involves such device.

Additionally, it would be inappropriate to apply a higher device offset percentage or increase the payment rate in the ASC setting simply because a device's invoice price is greater than the procedure's device offset amount. Our packaging policies are intended to promote the efficient use of resources both in the HOPD as well as ASC setting and these policies include the packaging of medical devices. While we provide separate transitional pass-through payments for devices for the cost of devices approved for transitional pass-through status, as we stated previously, the intent of transitional pass-through status for devices is to facilitate access for beneficiaries to the advantages of truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected. We believe it would be inappropriate to provide a similar method of calculating payment solely based on a device's cost or invoice price for devices that are not approved for transitional pass-through status.

Lastly, we have heard concerns from stakeholders regarding hospitals' coding decisions for particular devices. Specifically, stakeholders have contended that hospitals do not report HCPCS code C1889 for a particular insertable device as the NUBC billing guidelines recommend that such HCPCS code crosswalk to revenue code 0278—Other Implants—and this revenue code would be inappropriate for the costs attributable to devices that are insertable and not implantable. While we understand stakeholder concerns regarding accurate device cost reporting, we expect hospitals to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable. However, while we do not believe additional guidance from CMS or adjustment to the device offset calculation to exclude certain claims is warranted at this time, we will continue to monitor this issue going forward.

After reviewing the public comments we received, we are finalizing our proposal to assign a device offset percentage based on CY 2020 data if CY 2020 claims information is available, for procedures that were assigned device-intensive status, but, because CY 2019 claims data is not available, would otherwise be assigned a default device offset percentage of 31 percent or a device offset percentage based on claims from a clinically-similar code. Based on updated data for this CY 2022 OPPS/ASC final rule with comment period, we are applying device offset percentages from 2020 claims data to 14 procedures. *These include the 11 procedures described previously plus three additional procedures that were assigned default device offset percentages for CY 2021 and have available device offset percentages from CY 2020 claims data:*

- *CPT code 0519T (Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter));*
- *CPT code 0618T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange); and*
- *HCPCS code C9761 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy (ureteral catheterization is included) and vacuum aspiration of the kidney, collecting system and urethra if applicable).*

Additionally, in this final rule with comment period, we are correcting the device offset percentages for several new device-intensive procedures to reflect available claims data from predecessor codes.

The full listing of the final CY 2022 device-intensive procedures can be found in Addendum P to the CY 2022 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website). Further, our claims accounting narrative contains a description of our device offset percentage calculation. Our claims accounting narrative for this final rule with comment period can be found under supporting documentation for the CY 2022 OPPS/ASC final rule on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a—device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of

HCPCS code C1889 is ''Implantable/insertable device, not otherwise classified''.

We did not propose any changes to this policy for CY 2022.

Comment: Some commenters recommended that we reinstate specific device-to-procedure edits. One commenter recommended we reinstate specific device-to-procedure edits for arthroplasty procedures and another commenter recommended we reinstate specific device edits for C-code device-intensive procedures. One commenter contended that the removal of specific device-to-procedure edits has contributed to erosion in accuracy in the data highlighted by certain procedures having device offset percentages that are nearly 100 percent of the procedures' costs.

Response: As we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66794), we continue to believe that the elimination of device-to-procedure edits and procedure-to-device edits is appropriate due to the experience hospitals now have in coding and reporting these claims fully. More specifically, for the most costly devices, we believe the C–APCs reliably reflect the cost of the device if charges for the device are included anywhere on the claim. We note that, under our current policy, hospitals are still expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable. We also note that, as with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

Additionally, we have not observed any increase in frequency of procedures with device offset percentages that are nearly 100 percent; and we do not believe the absence of device-to-procedure edits has precipitated an erosion in accuracy of our device cost statistics. Procedures with extremely significant device offset percentages of greater than 90 percent can be attributed to procedures with little claims volume as well as extremely significant device costs and not the absence of device-to-procedure edits. Therefore, we are not accepting the commenters' recommendations to reinstate device-to-procedure edits.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the ''FD'' value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized a policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code ''FD'' when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the

amount of the credit. We adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including Chapter 4, Section 61.3.6 of the Medicare Claims Processing Manual. Further, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86017 through 86018, 86302), we made conforming changes to our regulations at § 419.45(b)(1) and (2) that codified this policy.

We did not propose any changes and we did not receive any public comments related to our policies regarding payment for no cost/full credit and partial credit devices in CY 2022.

5. Payment Policy for Low-Volume Device-Intensive Procedures

In CY 2016, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act and used the median cost (instead of the geometric mean cost per our standard methodology) to calculate the payment rate for the implantable miniature telescope procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), which is the only code assigned to APC 5494 (Level 4 Intraocular Procedures) (80 FR 70388). We noted that, as stated in the CY 2017 OPPS/ASC proposed rule (81 FR 45656), we proposed to reassign the procedure described by CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures) for CY 2017, but it would be the only procedure code assigned to APC 5495. The payment rates for a procedure described by CPT code 0308T (including the predecessor HCPCS code C9732) were $15,551 in CY 2014, $23,084 in CY 2015, and $17,551 in CY 2016. The procedure described by CPT code 0308T is a high-cost device-intensive surgical procedure that has a very low volume of claims (in part because most of the procedures described by CPT code 0308T are performed in ASCs). We believe that the median cost is a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate for this procedure because the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. We stated that, in future rulemaking, we would consider proposing a general policy for the payment rate calculation for very low-volume device-intensive APCs (80 FR 70389).

For CY 2017, we proposed and finalized a payment policy for low-volume device-intensive procedures that is similar to the policy applied to the procedure described by CPT code 0308T in CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79660 through 79661), we established our current policy that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be calculated using the median cost instead of the geometric mean cost, for the reasons described previously for the policy applied to the procedure described by CPT code 0308T in CY 2016. For CYs 2019 through 2021, we continued our policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC by using the median cost instead of the geometric mean (85 FR 86019).

As discussed in further detail in Section X.C of the CY 2022 OPPS/ASC proposed rule (86 FR 42181 through 42185), we proposed to establish a universal low volume APC policy for clinical APCs, brachytherapy APCs, and New Technology APCs with fewer than 100 single claims in the claims data used for ratesetting (for CY 2022 rates, this is proposed to be the CY 2019 claim data). For APCs designated as low volume APCs (those with fewer than 100 single claims in the claims year) under our proposed policy, we proposed to establish a payment rate using the highest of the median cost, arithmetic mean cost, or the geometric mean cost. In conjunction with our new, broader low volume APC proposal for clinical APCs, brachytherapy APCs, and New Technology APCs, we proposed to eliminate our payment policy for low-volume device-intensive procedures for CY 2022 and subsequent calendar years. Currently, CPT code 0308T is the only code subject to our low-volume device-intensive policy. Given that our proposed universal low volume APC policy would utilize a greater number of claims and provide additional cost metric alternatives for ratesetting than our existing low-volume device-intensive policy, we believe that the cost and ratesetting issues previously discussed with respect to CPT code 0308T would be appropriately addressed under our broader universal low volume APC proposal.

We did not receive any public comments on our proposal to eliminate our payment policy for low-volume device-intensive procedures and address low-volume, device-intensive procedures through our broader proposal to designate low volume APCs among eligible clinical APCs, brachytherapy APCs, and New Technology APCs and we are finalizing our proposal without modification. Public comments related to our proposed Low Volume APC policy are discussed in section X.C (Low Volume Policy for Clinical and Brachytherapy APCs) of this final rule with comment period.

V. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. Throughout the proposed rule, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. A ''biological'' as used in the proposed rule includes (but is not necessarily limited to) a ''biological product'' or a ''biologic'' as defined under section 351 of the PHS Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996, and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug as a hospital outpatient service under Medicare Part B. Proposed CY 2022 pass-through drugs and

biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to the proposed rule (which are available via the internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In the proposed rule, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

The pass-through application and review process for drugs and biologicals is described on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*.

2. Transitional Pass-Through Payment Period for Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Quarterly Expiration of Pass-Through Status

As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug or biological as a hospital outpatient service under Medicare Part B. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for newly approved pass-through drugs and biologicals on a quarterly basis through the next available OPPS quarterly update after the approval of a drug's or biological's pass-through status. However, prior to CY 2017, we expired pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), we finalized a policy change, beginning with pass-through drugs and biologicals newly approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for drugs, biologicals, and radiopharmaceuticals to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals.

This change eliminated the variability of the pass-through payment eligibility period, which previously varied based on when a particular application was initially received. We adopted this change for pass-through approvals beginning on or after CY 2017, to allow, on a prospective basis, for the maximum pass-through payment period for each pass-through drug without exceeding the statutory limit of 3 years. Notice of drugs whose pass-through payment status is ending during the calendar year will continue to be included in the quarterly OPPS Change Request transmittals.

Comment: One commenter commended CMS for continuing the policy to provide for quarterly expiration of pass-through payment status, which allows a pass-through period that is as close to a full 3 years as possible.

Response: We thank the commenter for their input and support of this policy, which was adopted in the CY 2017 OPPS/ASC final rule (81 FR 79654 through 79655).

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2021

There are 25 drugs and biologicals whose pass-through payment status will expire during CY 2021, as listed in Table 37. Most of these drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2018, through December 31, 2021. In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals newly approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed to be $130 for CY 2022), as discussed further in section V.B.1. of the CY 2022 OPPS/ASC proposed rule (86 FR 42127 through 42148). We proposed that if the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we proposed to provide separate payment at the applicable ASP-based payment amount (which is proposed at ASP+6 percent for non-340B drugs for CY 2022, as discussed further in section V.B.2. of the CY 2022 OPPS/ASC proposed rule (86 FR 42132).

We did not receive any public comments regarding our proposals. Therefore, we are adopting these proposals as final for CY 2022 without modification. Refer to Table 37 for the list of drugs and biologicals for which pass-through payment status will expire between March 31, 2021 and December 31, 2021. The packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B of the CY 2022 OPPS/ASC final rule (which is available via the internet on the CMS website).

BILLING CODE 4120–01–P

TABLE 37: DRUGS AND BIOLOGICALS FOR WHICH PASS - THROUGH PAYMENT STATUS WILL EXPIRE BETWEEN MARCH 31, 2021 AND DECEMBER 31, 2021

CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018	03/31/2021
J0185	Injection, aprepitant, 1 mg	G	9463	04/01/2018	03/31/2021
J0517	Injection, benralizumab, 1 mg	G	9466	04/01/2018	03/31/2021
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018	03/31/2021
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468	04/01/2018	03/31/2021
J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg	G	9174	04/01/2018	03/31/2021
J9311	lnjection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	03/31/2021
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9035	04/01/2018	03/31/2021
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018	03/31/2021

CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018	03/31/2021
A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie	G	9067	07/01/2018	06/30/2021
J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	G	9070	07/01/2018	06/30/2021
J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018	06/30/2021
J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018	06/30/2021
Q9991	Injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg	G	9073	07/01/2018	06/30/2021
Q9992	Injection, buprenorphine extended-release (sublocade), greater than 100 mg	G	9239	07/0/2018	06/30/2021
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018	09/30/2021
Q5105	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	G	9096	10/01/2018	09/30/2021
Q5106	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for non-esrd use), 1000 units	G	9097	10/01/2018	09/30/2021
A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9339	01/01/2019	12/31/2021
J0222	Injection, Patisiran, 0.1 mg	G	9180	01/01/2019	12/31/2021
J0291	Injection, plazomicin, 5 mg	G	9183	01/01/2019	12/31/2021
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2021

CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J2798	Injection, risperidone, (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2021
J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2021

BILLING CODE 4120–01–C

4. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Expiring in CY 2022

We proposed to end pass-through payment status in CY 2022 for 26 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status between April 1, 2019, and January 1, 2020, are listed in Table 28 of the CY 2022 OPPS/ASC proposed rule (86 FR 42121 through 42122). The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2022, are assigned status indicator ''G'' in Addenda A and B to the CY 2022 OPPS/ASC proposed rule (which are available via the internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For 2022, we proposed to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2022. We proposed that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals that are not policy-packaged as described in section V.B.1.c. (86 FR 42120) under the CY 2022 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2022 minus a payment offset for the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological as described in section V.A.6. of the CY 2022 OPPS/ASC proposed rule (86 FR 42126). We proposed this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure.

We proposed to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2022 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2022, consistent with our CY 2021 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2022, we proposed to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of the CY 2022 OPPS/ASC proposed rule (86 FR 42132)), the equivalent payment provided to pass-through drugs and biologicals without ASP information. Additional detail on the WAC+3 percent payment policy can be found in section V.B.2.b. of the CY 2022 OPPS/ASC proposed rule. If WAC information also is not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP. Refer to Table 38 below for the list of drugs and biologicals with pass-through payment status expiring during CY 2022.

BILLING CODE 4120–01–P

TABLE 38 DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING DURING CY 2022

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9046	C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	03/31/2022
J0642	J0642	Injection, levoleucovorin 0(khapzory), 0.5 mg	G	9334	01/01/2020	03/31/2022
J1095	J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	G	9172	04/01/2019	03/31/2022
J3031	J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	G	9197	04/01/2019	03/31/2022
J3245	J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	03/31/2022
J7169	J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	03/31/2022
J7208	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	03/31/2022
J9119	J9119	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	03/31/2022

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9313	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	03/31/2022
Q5108	Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	03/31/2022
Q5110	Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	03/31/2022
Q5111	Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	03/31/2022
C9047	C9047	Injection, caplacizumab-yhdp, 1 mg	G	9199	07/01/2019	06/30/2022
J0121	J0121	Injection, omadacycline, 1 mg	G	9311	07/01/2019	06/30/2022
J1096	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308	07/01/2019	06/30/2022
J1303	J1303	Injection, ravulizumab-cwvz, 10 mg	G	9312	07/01/2019	06/30/2022
J9036	J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	G	9313	07/01/2019	06/30/2022
J9210	J9210	Injection, emapalumab-lzsg, 1 mg	G	9310	07/01/2019	06/30/2022
J9269	J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	06/30/2022
J3111	J3111	Injection, romosozumab-aqqg, 1 mg	G	9327	10/01/2019	09/30/2022
J9356	J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	G	9314	10/01/2019	09/30/2022
C9054	J0691	Injection, lefamulin (xenleta), 1 mg	G	9332	01/01/2020	12/31/2022
C9055	J1632	Injection, brexanolone, 1mg	G	9333	01/01/2020	12/31/2022
J9309	J9309	Injection, polatuzumab vedotin-piiq, 1 mg	G	9331	01/01/2020	12/31/2022
Q5107	Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	12/31/2022
Q5117	Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	G	9330	01/01/2020	12/31/2022

BILLING CODE 4120–01–C

5. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Continuing in CY 2022

We proposed to continue pass-through payment status in CY 2022 for 46 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2020, and January 1, 2022, are listed in Table 39. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will continue after December 31, 2022, are assigned status indicator ''G'' in Addenda A and B to the CY 2022 OPPS/ASC proposed rule (which are available via the internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For 2023, we proposed to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2022. We proposed that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals that are not policy-packaged as described in section V.B.1.c. under the CY 2022 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+6 percent, is $0. In the case of policy-packaged drugs (which include the following: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2022 minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6. of the CY 2022 OPPS/ASC proposed rule (86 FR 42126). We proposed this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure.

We proposed to continue to update pass-through payment rates on a quarterly basis on our website during CY 2022 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2022, consistent with our CY 2021 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2023, we proposed to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of the CY 2022 OPPS/ASC proposed rule (86 FR 42132)), the equivalent payment provided to pass-through drugs and biologicals without ASP information. Additional detail on the WAC+3 percent payment policy can be found in section V.B.2.b. of the CY 2022 OPPS/ASC proposed rule. If WAC information also is not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The drugs and biologicals that we proposed to have pass-through payment status expire after December 31, 2022, are shown in Table 39.

BILLING CODE 4120–01–P

TABLE 39: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING AFTER CY 2022

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0179	J0179	Injection, brolucizumab-dbll, 1 mg	G	9340	04/01/2020	03/31/2023
J0223	J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
J0791	J0791	Injection, crizanlizumab-tmca, 1 mg	G	9359	04/01/2020	03/31/2023
J1201	J1201	Injection, cetirizine hydrochloride, 1 mg	G	9361	04/01/2020	03/31/2023
J7331	J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023
Q5114	Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
Q5120	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362	07/01/2020	06/30/2023
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J1429	J1429	Injection, golodirsen, 10 mg	G	9356	07/01/2020	06/30/2023

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J1738	J1738	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
J3032	J3032	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023
J3241	J3241	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354	07/01/2020	06/30/2023
J7402	J7402	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364	07/01/2020	06/30/2023
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023
Q5116	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	G	9350	07/01/2020	06/30/2023
Q5118	Q5118	Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg	G	9348	07/01/2020	06/30/2023
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367	07/01/2020	06/30/2023

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9591	A9591	Fluoroestradiol F 18, diagnostic, 1 millicurie	G	9370	10/01/2020	09/30/2023
C9067	C9067	Gallium ga-68, dotatoc, diagnostic, 0.01 mCi	G	9323	10/01/2020	09/30/2023
J7351	J7351	Injection, bimatoprost, intracameral implant, 1 microgram	G	9351	10/01/2020	09/30/2023
J9144	J9144	Injection, daratumumab, 10 mg and hyaluronidase-fihj	G	9378	10/01/2020	09/30/2023
J9227	J9227	Injection, isatuximab-irfc, 10 mg	G	9377	10/01/2020	09/30/2023
J9281	J9281	Mitomycin pyelocalyceal instillation, 1 mg	G	9374	10/01/2020	09/30/2023
J9317	J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg	G	9376	10/01/2020	09/30/2023
Q5112	Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg	G	9382	10/01/2020	09/30/2023
Q5113	Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg	G	9349	10/01/2020	09/30/2023
Q5121	Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	G	9381	10/01/2020	09/30/2023
J1437	J1437	Injection, ferric derisomaltose, 10 mg	G	9388	01/01/2021	12/31/2023

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9198	J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	G	9387	01/01/2021	12/31/2023
A9592	A9592	Copper Cu-64, dotatate, diagnostic, 1 millicurie	G	9383	01/01/2021	12/31/2023
J1427	J1427	Injection, viltolarsen, 10 mg	G	9386	01/01/2021	12/31/2023
J1554	J1554	Injection, immune globulin (Asceniv), 500 mg	G	9392	01/01/2021	12/31/2023
J9037	J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	G	9384	01/01/2021	12/31/2023
J9223	J9223	Injection, lurbinectedin, 0.1 mg	G	9389	01/01/2021	12/31/2023
J9316	J9316	Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg	G	9390	01/01/2021	12/31/2023
J9349	J9349	Injection, tafasitamab-cxix, 2 mg	G	9385	01/01/2021	12/31/2023
Q2053	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9391	01/01/2021	12/31/2023
Q5122	Q5122	Injection, pegfilgrastim-apgf,	G	9406	04/01/2021	12/31/2023

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		biosimilar, (nyvepria), 0.5 mg				
J0224	J0224	Injection, lumasiran, 0.5 mg	G	9407	04/01/2021	03/31/2024
J7212	J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram	G	9395	04/01/2021	03/31/2024
Q5122	Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	G	9406	04/01/2021	03/31/2024
A9593	A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	G	9409	07/01/2021	06/30/2024
A9594	A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	G	9410	07/01/2021	06/30/2024
J0741	J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414	07/01/2021	06/30/2024
J1305	J1305	Injection, evinacumab-dgnb, 5mg	G	9416	07/01/2021	06/30/2024
J1426	J1426	Injection, casimersen, 10 mg	G	9412	07/01/2021	06/30/2024
J1448	J1448	Injection, trilaciclib, 1mg	G	9415	07/01/2021	06/30/2024
J9247	J9247	Injection, melphalan flufenamide, 1mg	G	9417	07/01/2021	06/30/2024
J9348	J9348	Injection, naxitamab-gqgk, 1 mg	G	9408	07/01/2021	06/30/2024

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9353	J9353	Injection, margetuximab-cmkb, 5 mg	G	9418	07/01/2021	06/30/2024
Q2054	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9413	07/01/2021	06/30/2024
C9081	Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9422	10/01/2021	09/30/2024
C9082	J9272	Injection, dostarlimab-gxly, 100 mg	G	9423	10/01/2021	09/30/2024
C9083	J0961	Injection, amivantamab-vmjw, 10 mg	G	9424	10/01/2021	09/30/2024
C9084	C9084	Injection, loncastuximab tesirine-lpyl, 0.1 mg	G	9425	10/01/2021	09/30/2024
J1823	J1823	Injection, inebilizumab-cdon, 1 mg	G	9394	10/01/2021	09/30/2024

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J2406	J2406	Injection, oritavancin (kimyrsa), 10 mg	G	9427	10/01/2021	09/30/2024
N/A	A9595	Piflufolastat f-18, diagnostic, 1 millicurie	G	9430	01/01/2022	12/31/2024
N/A	C9085	Injection, avalglucosidase alfa-ngpt, 2 mg	G	9433	01/01/2022	12/31/2024
N/A	C9086	Injection, anifrolumab-fnia, 1 mg	G	9434	01/01/2022	12/31/2024
N/A	C9087	Injection, cyclophosphamide, (auromedics), 10 mg	G	9435	01/01/2022	12/31/2024

6. Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals to Offset Costs Packaged Into APC Groups

Under the regulation at 42 CFR 419.2(b), nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged in the OPPS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. Also, under the regulation at 42 CFR 419.2(b), nonpass-through drugs and biologicals that function as supplies in a surgical procedure are packaged in the OPPS. This category includes skin substitutes and other surgical-supply drugs and biologicals. As described earlier, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for policy-packaged drugs, biologicals, and radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made. This amount reflecting the portion of the APC payment associated with predecessor products is called the payment offset.

The payment offset policy applies to all policy-packaged drugs, biologicals, and radiopharmaceuticals. For a full description of the payment offset policy as applied to policy-packaged drugs, which include diagnostic radiopharmaceuticals, contrast agents, stress agents, and skin substitutes, we refer readers to the discussion in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70430 through 70432). For CY 2022, as we did in CY 2021, we proposed to continue to apply the same policy-packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. The proposed APCs to which a payment offset may be applicable for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes are identified in Table 40.

TABLE 40: APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2022

CY 2022 APC	CY 2022 APC Title
Diagnostic Radiopharmaceutical	
5591	Level 1 Nuclear Medicine and Related Services
5592	Level 2 Nuclear Medicine and Related Services
5593	Level 3 Nuclear Medicine and Related Services
5594	Level 4 Nuclear Medicine and Related Services
Contrast Agent	
5571	Level 1 Imaging with Contrast
5572	Level 2 Imaging with Contrast
5573	Level 3 Imaging with Contrast
Stress Agent	
5722	Level 2 Diagnostic Tests and Related Services
5593	Level 3 Nuclear Medicine and Related Services
Skin Substitute	
5054	Level 4 Skin Procedures
5055	Level 5 Skin Procedures

BILLING CODE 4120–01–C

We proposed to continue to post annually on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html* a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through payment device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC.

Comment: One commenter requested that CMS release a copy of the APC offset file with future OPPS/ASC proposed rules to enable the public to calculate the percentage of APC payment associated with packaged drug costs using APC offset data for the upcoming calendar year.

Response: We thank the commenter for their suggestion, and we will consider addressing this request in future rulemaking.

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $130 for CY 2021 (84 FR 61312 through 61313).

Following the CY 2007 methodology, for the CY 2022 OPPS/ASC proposed rule, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2022 and rounded the resulting dollar amount ($132.44) to the nearest $5 increment, which yielded a figure of $130. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from CMS's Office of the Actuary. For the CY 2022 OPPS/ASC proposed rule, based on these calculations using the CY 2007 OPPS methodology, we proposed a packaging threshold for CY 2022 of $130.

Comment: Two commenters expressed their support for maintaining the drug packaging threshold for CY 2022 at $130. One commenter believes, however, that the drug packaging threshold has been increasing faster than payment increases under the OPPS. This commenter would like us to research if the drug packaging threshold should be lowered in future years.

Response: We appreciate the support of the commenters of the drug packaging threshold level of $130. We also thank the one commenter for their suggestion to consider reducing the drug packaging threshold in future years and will consider it for future rulemaking.

After consideration of the public comments, we repeated our drug packaging threshold calculations for the final rule with the most current data available. Once again, we calculated a drug packaging threshold for CY 2022 of

$130. Therefore, we are finalizing our proposal without modification to have a drug packaging threshold for CY 2022 of $130.

b. Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Certain Therapeutic Radiopharmaceuticals Under the Cost Threshold (''Threshold-Packaged Drugs'')

To determine the proposed CY 2022 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals that had a HCPCS code in CY 2019 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2019 claims processed through June 30, 2020, for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d. of the CY 2022 OPPS/ASC proposed rule (86 FR 42129), or for the following policy-packaged items that we proposed to continue to package in CY 2022: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2022, we use the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we proposed for separately payable drugs and biologicals (other than 340B drugs)) for CY 2022, as discussed in more detail in section V.B.2.b. of the proposed rule) to calculate the CY 2022 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2020 (data that were used for payment purposes in the physician's office setting, effective April 1, 2021) to determine the proposed rule per day cost. While the CY 2020 ASP data were collected during the PHE, ASP data are not affected by changes in utilization the way non-drug services are for setting payment rates, and so we believe CY 2020 ASP data continues to be representative of the price of drugs in the market. We have continued to use ASP data from CY 2020 to report quarterly drug rates for CY 2020 and CY 2021.

As is our standard methodology, for 2022, we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2020 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the proposed rule (which are available via the internet on the CMS website) because these are the most recent data available for use at the time of development of the proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2021. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2019 hospital claims data to determine their per day cost.

We proposed to package items with a per day cost less than or equal to $130, and identify items with a per day cost greater than $130 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2019 HCPCS codes that were reported to the CY 2021 HCPCS codes that we display in Addendum B to the CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website) for proposed payment in CY 2022.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in the CY 2022 OPPS/ASC proposed rule, we proposed to use ASP data from the fourth quarter of CY 2020, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2021, along with updated hospital claims data from CY 2019. We note that we also proposed to use these data for budget neutrality estimates and impact analyses for the CY 2022 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of the final rule with comment period will be based on ASP data from the second quarter of CY 2021. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2021. These payment rates would then be updated in the January 2022 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2022. For items that do not currently have an ASP-based payment rate, we proposed to recalculate their mean unit cost from all of the CY 2019 claims data and update cost report information available for the CY 2022 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for the final rule with comment period. Under such circumstances, we proposed to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2022 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2021. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2022, consistent with our historical practice, we proposed to apply the following policies to these HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2021 and that are proposed for separate payment in CY 2022, and that then have per day costs equal to or less than the CY 2022 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2022 final rule, would continue to receive separate payment in CY 2022.
- HCPCS codes for drugs and biologicals that were packaged in CY 2021 and that are proposed for separate payment in CY 2022, and that then have

per day costs equal to or less than the CY 2022 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2022 final rule, would remain packaged in CY 2022.

- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2022 but that then have per-day costs greater than the CY 2022 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2022 final rule, would receive separate payment in CY 2022.

We did not receive any public comments on our proposal to recalculate the mean unit cost for items that do not currently have an ASP-based payment rate from all of the CY 2019 claims data and updated cost report information available for this CY 2022 final rule with comment period to determine their final per day cost. We also did not receive any public comments on our proposal to continue to follow the established policies, initially adopted for the CY 2005 OPPS (69 FR 65780), when the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the final rule with comment period. For CY 2022, we are finalizing these two proposals without modification. Please refer to Addendum B to this final rule with comment period, which is available via the internet on the CMS website, for information on the packaging status of drugs, biologicals, and therapeutic radiopharmaceuticals.

c. Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));
- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including, but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than that at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: ''We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy'' (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

Comment: One commenter requested that we develop a policy to provide separate payment for drugs that are administered at the time of ophthalmic surgery and have an FDA-approved indication to treat or prevent postoperative issues.

Response: A surgical procedure episode consists of both pre-operative and post-operative care in addition to the surgical procedure itself. If a drug used to address a post-operative concern, such as pain management, is billed together with a surgical procedure, we assume that the pain management drug was given as a part of the overall surgical procedure. Since the pain management drug is ancillary to the primary ophthalmic surgery procedure, it is considered a surgical supply. The pain management drug is only administered to the patient because the patient has received ophthalmic surgery, and the drug would not have been administered to the patient if the patient did not have the surgery. In the OPPS, we pay one rate for the entire surgical procedure, and payment for supplies, such as pain management drugs, is packaged into the payment rate for the surgical procedure. We note exceptions to this policy in the ASC setting are discussed in II.A.3.b. (Payment Policy for Non-Opioid Pain Management Drugs and Biologicals that Function as Surgical Supplies under the ASC Payment System) of this final rule with comment period.

Comment: One commenter recommended that CMS continue to apply radiolabeled product edits to the nuclear medicine procedures to ensure that all packaged costs are included on nuclear medicine claims in order to establish appropriate payment rates in the future. The commenter was concerned that many providers performing nuclear medicine procedures are not including the cost of diagnostic radiopharmaceuticals used for the procedures in their claims submissions. The commenter believes this lack of drug cost reporting could be causing the cost of nuclear medicine procedures to be underreported and therefore request that the radiolabeled product edits be reinstated.

Response: We appreciated the commenter's feedback; however, we are not reinstating the radiolabeled product edits to nuclear medicine procedures, which required a diagnostic radiopharmaceutical to be present on the same claim as a nuclear medicine procedure for payment to be made under the OPPS. As previously discussed in the CY 2020 OPPS/ASC final rule with comment period (85 FR 86033 through 86034), the edits were in place between CY 2008 and CY 2014 (78 FR 75033). We believe the period of time in which the edits were in place was sufficient for hospitals to gain experience reporting procedures involving radiolabeled products and to become accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of those radiolabeled products. As with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

Comment: Several commenters requested that diagnostic radiopharmaceuticals be paid separately in all cases, not just when the drugs have pass-through payment status. One commenter suggested payment based upon ASP, WAC, AWP, or mean unit cost data derived from hospital claims. Some commenters mentioned that pass-through payment status helps the diffusion of new diagnostic radiopharmaceuticals into the market, but is not enough to make up for what the commenters believe is inadequate payment after pass-through status

expires. Commenters opposed incorporating the cost of the drug into the associated APC, and provided evidence showing procedures in which diagnostic radiopharmaceuticals are considered to be a surgical supply, which the commenter believed are often paid at a lower rate than the payment rate for the diagnostic radiopharmaceutical itself when the drug had pass-through payment status. Additionally, commenters proposed alternative payment methodologies such as subjecting diagnostic radiopharmaceuticals to the drug packaging threshold, creating separate APC payments for diagnostic radiopharmaceuticals that cost more than $500, or using ASP, WAC, or AWP to account for packaged radiopharmaceutical costs.

Response: We thank commenters for their suggestions. Commenters have made many of these suggestions in the past and we addressed them in previous rules, including the CY 2020 OPPS/ASC final rule (84 FR 61314 through 61315) and the CY 2021 OPPS/ASC final rule (85 FR 86034). We continue to believe that diagnostic radiopharmaceuticals are an integral component of many nuclear medicine and imaging procedures and charges associated with them should be reported on hospital claims to the extent they are used, and accordingly, the payment for the radiopharmaceuticals is reflected within the payment for the primary procedure.

In response to the comment regarding the proposed cost of the packaged procedure in CY 2022 being substantially lower than the payment rate of the radiopharmaceutical when it was on pass-through payment status plus the payment rate of the procedure associated with the radiopharmaceutical, we note that rates are established in a manner that uses the geometric mean of reported costs to furnish the procedure based on data submitted to CMS from all hospitals paid under the OPPS to set the payment rate for the service. Accordingly, the costs that are calculated by Medicare reflect the average costs of items and services that are packaged into a primary procedure and will not necessarily equal the sum of the cost of the primary procedure and the average sales price of the specific items and services used in the procedure in each case. Furthermore, the costs will be based on the reported costs submitted to Medicare by the hospitals and not the list price established by the manufacturer. Claims data that include the radiopharmaceutical packaged with the associated procedure reflect the combined cost of the procedure and the radiopharmaceutical used in the procedure. Additionally, we do not believe it is appropriate to create a new packaging threshold specifically for diagnostic radiopharmaceuticals as such a threshold would not align with our overall packaging policy and commenters have submitted only limited data to support a specific threshold.

With respect to the request that we create a new APC for each radiopharmaceutical product, we do not believe it is appropriate to create unique APCs for diagnostic radiopharmaceuticals. Diagnostic radiopharmaceuticals function as supplies during a diagnostic test or procedure and following our longstanding packaging policy, these items are packaged under the OPPS. Packaging supports our goal of making OPPS payments consistent with those of a prospective payment system, which packages costs into a single aggregate payment for a service, encounter, or episode of care. Furthermore, diagnostic radiopharmaceuticals function as supplies that enable the provision of an independent service, and are not themselves the primary therapeutic modality, and therefore, we do not believe they warrant separate payment through creation of a unique APC at this time. We welcome ongoing dialogue with stakeholders regarding suggestions for payment changes for consideration in future rulemaking.

Comment: One commenter expressed their approval of the drugs proposed to be included in our policy-packaged drug policy.

Response: We appreciate the support of the commenter.

After consideration of the public comments we received, we are finalizing our proposals without modification to continue our drug packaging policies, which are included in the regulation text 42 CFR 419.2(b).

d. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we proposed to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2022.

For CY 2022, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2019 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for the CY 2022 OPPS/ASC proposed rule, and as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2019 claims data to make the proposed packaging determinations for these drugs: HCPCS code C9257 (Injection, bevacizumab, 0.25 mg); HCPCS code J1840 (Injection, kanamycin sulfate, up to 500 mg); HCPCS code J1850 (Injection, kanamycin sulfate, up to 75 mg); HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); HCPCS code J7100 (Infusion, dextran 40, 500 ml); and HCPCS code J7110 (Infusion, dextran 75, 500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP+6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to the proposed CY 2022 drug packaging threshold of $130 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2022 drug packaging threshold of $130 (so that all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2022 is displayed in Table 41.

Comment: One commenter supported our proposal to continue our current policy to make packaging determinations on a drug-specific basis rather than a HCPCS code basis when multiple HCPCS codes are used to describe different quantities of a drug or biological.

Response: We appreciate the support of the commenter.

After reviewing the public comments, we are finalizing our proposal, without modification, to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages. The packaging status of each drug and biological HCPCS code to which this methodology applies in CY 2022 is displayed in Table 41.

BILLING CODE 4120–01–P

TABLE 41: HCPCS CODES TO WHICH THE CY 2022 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2022 HCPCS Code	CY 2022 Long Descriptor	CY 2022 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

BILLING CODE 4120–01–C

2. Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). We refer to this alternative methodology as the ''statutory default.'' Most physician Part B drugs are paid at ASP+6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.[176]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In the CY 2022 OPPS/ASC proposed rule, we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We have continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2021.

b. CY 2022 Payment Policy

For 2022, we proposed to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals, with the exception of 340B-acquired drugs, at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We proposed to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent (as described in section V.B.6). We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055) for more information about our current payment policy for drugs and biologicals acquired with a 340B discount.

In the case of a drug or biological during an initial sales period in which data on the prices for sales of the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II) of the Act, the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS final rule, under section 1847A(c)(4) of the Act, although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data is not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3-percent add-on in place of the 6-percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). For CYs 2020 and 2021, we adopted a policy to utilize a 3-percent add-on instead of a 6-percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act pursuant to our authority under section 1833(t)(14)(A)(iii)(II) (84 FR 61318 and 85 FR 86039). For 2022, we proposed to continue to utilize a 3-percent add-on instead of a 6-percent add-on for drugs that are paid based on WAC pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act, which

[176] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: *http://www.medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0.*

provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also proposed to apply this provision to non-SCOD separately payable drugs. Because we proposed to establish the average price for a drug paid based on WAC under section 1847A of the Act as WAC+3 percent instead of WAC+6 percent, we believe it is appropriate to price separately payable drugs paid based on WAC at the same amount under the OPPS. We proposed that, if finalized, our proposal to pay for drugs or biologicals at WAC+3 percent, rather than WAC+6 percent, would apply whenever WAC-based pricing is used for a drug or biological under 1847A(c)(4). For drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, the payment amount for these drugs (proposed as a rate of WAC minus 22.5 percent) would continue to apply. We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy.

We proposed that payments for separately payable drugs and biologicals would be included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. We also proposed that the budget neutral weight scalar would not be applied in determining payments for these separately payable drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to the CY 2022 OPPS/ASC proposed rule (available via the internet on the CMS website), which illustrate the proposed CY 2022 payment of ASP+6 percent for separately payable nonpass-through drugs and biologicals and ASP+6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective April 1, 2021, or WAC, AWP, or mean unit cost from CY 2019 claims data and updated cost report information available for the CY 2022 OPPS/ASC proposed rule. In general, these published payment rates are not the same as the actual January 2022 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2022 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2021 (July 1, 2021, through September 30, 2021) will be used to set the payment rates that are released for the quarter beginning in January 2022 in December 2021. In addition, payment rates for drugs and biologicals in Addenda A and B to the proposed rule for which there was no ASP information available for April 2021 are based on mean unit cost in the available CY 2019 claims data. If ASP information becomes available for payment for the quarter beginning in January 2022, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for the proposed rule (reflecting April 2021 ASP data) that do not have ASP information available for the quarter beginning in January 2022. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2019 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to the proposed rule are not for January 2022 payment purposes and are only illustrative of the CY 2022 OPPS payment methodology using the most recently available information at the time of issuance of the proposed rule.

Comment: Multiple commenters expressed their support for paying for separately payable drugs and biologicals at ASP+6 percent. The commenters believe this policy is consistent with statute and Congressional intent, and generates more predictable payment for providers than previous payment methodologies for drugs and biologicals. The commenters believe the ASP+6 percent payment policy ensures equivalent payment for drugs and biologicals between the outpatient hospital setting and the physician office, which encourages Medicare beneficiaries to receive care in the most clinically appropriate setting.

Response: We appreciate the commenters' feedback.

Comment: One commenter requested that an add-on percentage of greater than 6 percent of ASP be paid for separately payable radiopharmaceuticals to reflect higher overhead and handling costs for these products.

Response: The add-on percentage of 6 percent is generally viewed as reflecting the overhead and handling cost of most drugs, radiopharmaceuticals, and biologicals that are separately payable in the OPPS even though the overhead and handling costs for individual products may be higher or lower than 6 percent of the ASP. We believe that the add-on percentage of 6 percent is appropriate for separately payable radiopharmaceuticals.

Comment: Two commenters requested that we exclude both diagnostic and therapeutic radiopharmaceuticals from our proposed policy that during an initial sales period in which data on the prices for sales of the drug or biological are not sufficiently available from the manufacturer, that payments can be made for drugs using WAC pricing plus a 3 percent price add-on. The commenters believe the cost of preparing radiopharmaceuticals is higher than the cost of preparing other drugs and biologicals and a 6 percent price add-on should be required anytime that we use WAC to price a radiopharmaceutical.

Response: The WAC of a drug or biological is defined in section 1847A(c)(6)(B) of the Act as the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. Because the WAC does not include discounts, it typically exceeds ASP, and the use of a WAC-based payment amount for the same drug results in higher dollar payments than the use of an ASP-based payment amount. Also, MedPAC in their June 2017 Report to the Congress (*http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf*, pages 42 through 44) suggested that greater parity between ASP-based acquisition costs and WAC-based payments for Part B drugs could be achieved and recommended changing the 6 percent add-on for WAC-based payments to 3 percent. Given this evidence that WAC pricing tends to overestimate drug cost, we believe our current and proposed policy to pay drugs at WAC plus 3 percent for all drugs, biologicals, and radiopharmaceuticals when ASP is not available more accurately reflects the cost of new products recently entering the market than does WAC plus 6 percent.

After considering the public comments we received, we are finalizing our proposals related to payment for SCODs and other separately payable drugs and biologicals without modification.

c. Biosimilar Biological Products

For CY 2016 and CY 2017, we finalized a policy to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the

Act and to subject nonpass-through biosimilar biological products to our annual threshold-packaged policy (for CY 2016, 80 FR 70445 through 70446; and for CY 2017, 81 FR 79674). In the CY 2018 OPPS/ASC proposed rule (82 FR 33630), for CY 2018, we proposed to continue this same payment policy for biosimilar biological products.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), we noted that, with respect to comments we received regarding OPPS payment for biosimilar biological products, in the CY 2018 PFS final rule, CMS finalized a policy to implement separate HCPCS codes for biosimilar biological products. Therefore, consistent with our established OPPS drug, biological, and radiopharmaceutical payment policy, HCPCS coding for biosimilar biological products is based on the policy established under the CY 2018 PFS final rule.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), after consideration of the public comments we received, we finalized our proposed payment policy for biosimilar biological products, with the following technical correction: All biosimilar biological products are eligible for pass-through payment and not just the first biosimilar biological product for a reference product. In the CY 2019 OPPS/ASC proposed rule (83 FR 37123), for CY 2019, we proposed to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

In addition, in CY 2018, we adopted a policy that biosimilars without pass-through payment status that were acquired under the 340B Program would be paid the ASP of the biosimilar minus 22.5 percent of the reference product's ASP (82 FR 59367). We adopted this policy in the CY 2018 OPPS/ASC final rule with comment period because we believe that biosimilars without pass-through payment status acquired under the 340B Program should be treated in the same manner as other drugs and biologicals acquired through the 340B Program. As noted earlier, biosimilars with pass-through payment status are paid their own ASP+6 percent of the reference product's ASP. Separately payable biosimilars that do not have pass-through payment status and are not acquired under the 340B Program are also paid their own ASP plus 6 percent of the reference product's ASP. If a biosimilar does not have ASP pricing, but instead has WAC pricing, the WAC pricing add-on of either 3 percent or 6 percent is calculated from the biosimilar's WAC and is not calculated from the WAC price of the reference product.

As noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), several stakeholders raised concerns to us that the payment policy for biosimilars acquired under the 340B Program could unfairly lower the OPPS payment for biosimilars not on pass-through payment status because the payment reduction would be based on the reference product's ASP, which would generally be expected to be priced higher than the biosimilar, thus resulting in a more significant reduction in payment than if the 22.5 percent was calculated based on the biosimilar's ASP. We agreed with stakeholders that the current payment policy could unfairly lower the price of biosimilars without pass-through payment status that are acquired under the 340B Program. In addition, we noted that we believed that these changes would better reflect the resources and production costs that biosimilar manufacturers incur. We also stated that we believe this approach is more consistent with the payment methodology for 340B-acquired drugs and biologicals, for which the 22.5 percent reduction is calculated based on the drug or biological's ASP, rather than the ASP of another product. In addition, we explained that we believed that paying for biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP, rather than 22.5 percent of the reference product's ASP, will more closely approximate hospitals' acquisition costs for these products.

Accordingly, in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), we proposed changes to our Medicare Part B drug payment methodology for biosimilars acquired under the 340B Program. Specifically, for CY 2019 and subsequent years, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP. This proposal was finalized without modification in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58977).

For 2022, we proposed to continue our policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. We also proposed to continue our current policy of paying for nonpass-through biosimilars acquired under the 340B program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act.

Comment: One commenter supported our proposal to continue our policy from CY 2018 to make biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

Response: We appreciate the commenter's support of this established policy.

Comment: Multiple commenters supported our proposal to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP, rather than the reference product's ASP.

Response: We appreciate the commenters' support. Please see section V.B.6. of this final rule with comment period for a discussion of payment policy for drugs and biologicals acquired under the 340B program.

Comment: One commenter did not support our proposal to continue our CY 2018 policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. The commenter believes that there should be a ''level playing field'' between biosimilars and their reference products in order to increase competition and reduce costs for beneficiaries. The commenter does not believe it is fair for biosimilars of a reference product to be receiving passthrough payment of ASP plus 6 percent of the reference product's ASP. The commenter pointed out that when the reference product is no longer eligible for pass-through payment, if it is acquired under the 340B program, hospitals would be paid for the product at ASP minus 22.5 percent, while the biosimilar that has pass-through status continues to receive payment at ASP plus 6 percent of the reference product's ASP. The commenter believes that this difference in the payment rates for biosimilars and their reference products could potentially lead to increased Medicare spending on biosimilars as providers utilize biosimilars instead of the biosimilars' reference products because of the higher payment rates for biosimilars in these circumstances.

Response: As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58977), we continue to believe that eligibility for pass-through payment status reflects the unique, complex nature of biosimilars

and is important as biosimilars become established in the market, just as it is for all other new drugs and biologicals. In terms of the potential increased payment for biosimilars under our policy to allow biosimilars to be eligible for pass-through status, overall increased competition due to the presence of more biosimilars on the market as a result of this policy is expected to drive payments down for both Medicare and for beneficiaries over time, even if there may be increased spending on biosimilars in the short term.

After consideration of the public comments we received, we are finalizing our proposed payment policy for biosimilar products, without modification, to continue the policy established in CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. We are also finalizing our proposal to continue to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's, rather than the reference product's ASP. Our final policy regarding the payment rate for drugs and biologicals that are acquired under the 340B program is described in section V.B.6 of this final rule with comment period.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2022, we proposed to continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. We pay for separately payable therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals in CY 2022. Therefore, we proposed for CY 2022 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also proposed to rely on CY 2019 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information is unavailable. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524). The proposed CY 2022 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to the CY 2022 OPPS/ASC proposed rule (which are available via the internet on the CMS website).

Comment: One commenter supported the continuation of this policy to provide a predicable payment methodology and avoid the payment swings that occurred prior to adoption of the statutory default rate for therapeutic radiopharmaceuticals.

Response: We thank the commenter for their support.

We did not receive any additional public comments on this proposal and are finalizing our proposal, without modification, to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent. We are also finalizing our proposal to continue to rely on CY 2019 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable. The CY 2022 final payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website).

4. Payment for Blood Clotting Factors

For CY 2021, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (85 FR 86041). That is, for CY 2021, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2021 updated furnishing fee was $0.238 per unit.

For 2022, we proposed to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the PFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we proposed to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

We proposed to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website.

Comment: One commenter supports our proposal to continue to pay for blood clotting factors at ASP+6 percent plus a furnishing fee for the clotting factor update annually using the CPI. The commenter also supports our policy to pay the same clotting factor

furnishing fee in both the hospital outpatient and physician office settings.

Response: We appreciate the commenter's support for our policies.

After reviewing the public comment that we received, we are finalizing our proposal, without modification, to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website.

5. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPPS Hospital Claims Data

For CY 2022, we proposed to continue to use the same payment policy as in CY 2021 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data, which describes how we determine the payment rate for drugs, biologicals, or radiopharmaceuticals without an ASP. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). The proposed CY 2022 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to the CY 2022 OPPS/ASC proposed rule, which is available via the internet on the CMS website.

We did not receive any comments on our proposal. Therefore, we are finalizing our CY 2022 proposal without modification, including our proposal to assign drug or biological products status indicator ''K'' and pay for them separately for the remainder of CY 2022 if pricing information becomes available. The CY 2022 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this final rule with comment period, which is available via the internet on the CMS website.

6. CY 2022 OPPS Payment Methodology for 340B Purchased Drugs

a. Overview

Under the OPPS, payment rates for drugs are generally provided for in section 1833(t)(14)(A). Under that provision, the payment amount is more specifically set forth by cross-reference to section 1847A, which generally sets a default rate of ASP+6 percent for certain drugs; however, the Secretary has statutory authority to adjust that rate under the OPPS. As described below, beginning in CY 2018, the Secretary adjusted the 340B drug payment rate to ASP minus 22.5 percent to approximate a minimum average discount for 340B drugs, which was based on findings of the GAO and MedPAC that hospitals were acquiring drugs at a significant discount under HRSA's 340B Drug Pricing Program. As described in the following sections, in December 2018, the United States District Court for the District of Columbia (the district court) concluded that the Secretary lacks the authority to bring the default rate in line with average acquisition cost unless the Secretary obtains survey data from hospitals on their acquisition costs. On July 10, 2019, the district court entered final judgment. The agency appealed to the United States Court of Appeals for the District of Columbia Circuit (hereinafter referred to as ''the D.C. Circuit''), and on July 31, 2020, the court entered an opinion reversing the district court's judgment in this matter. Following the D.C. Circuit's reversal of the lower court's decision, appellees' petition for panel rehearing and petition for rehearing en banc were denied on October 16, 2020. For CY 2021, CMS continued its policy of paying for drugs and biologicals acquired through the 340B Program at ASP minus 22.5 percent.

On January 10, 2021, the appellees filed a petition for a writ of certiorari in the United States Supreme Court. On July 2, 2021, the Supreme Court granted their petition for a writ of certiorari and directed the parties to argue whether the petitioners' suit challenging HHS's 340B drugs payment adjustment is precluded by section 1833(t)(12).[177]

b. Background

In the CY 2018 OPPS/ASC proposed rule (82 FR 33558 through 33724), we proposed changes to the OPPS payment methodology for drugs and biologicals (hereinafter referred to collectively as ''drugs'') acquired under the 340B Program. We proposed these changes to better, and more accurately, reflect the resources and acquisition costs that these hospitals incur. We stated our belief that such changes would allow Medicare beneficiaries (and the Medicare program) to pay a more appropriate amount when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program. Subsequently, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we finalized our proposal and adjusted the payment rate for separately payable drugs and biologicals (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program from ASP+6 percent to ASP minus 22.5 percent. We stated that our goal was to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs, while recognizing the intent of the 340B Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients. Congress created the 340B Drug Pricing Program so that the eligible entities—safety net providers identified in the statute—could stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. By design, the 340B Program increases the resources available to these safety net providers by providing discounts on covered outpatient drugs that generate savings that can be used to support patient care or other services. When the program was created, there was an understanding that many of the patients seen by these safety net providers were Medicare and Medicaid beneficiaries. This rule aims to fulfill the goals of different Federal programs, each of which helps ensure access to care for vulnerable populations. We note, however, that the 340B program does not contemplate subsidization from Medicare in the form of payments far exceeding hospitals' acquisition costs. We also note that critical access hospitals are not paid under the OPPS, and therefore are not subject to the OPPS payment policy for 340B-acquired drugs. We also excepted rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment in CY 2018. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change does not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or vaccines, which are excluded from the 340B Program.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699

[177] *https://www.supremecourt.gov/orders/courtorders/070221zor_4gc5.pdf.* Accessed July 8, 2021.

through 79706), we implemented section 603 of the Bipartisan Budget Act of 2015. As a general matter, applicable items and services furnished in certain off-campus outpatient departments of a provider on or after January 1, 2017, are not considered covered outpatient services for purposes of payment under the OPPS and are paid ''under the applicable payment system,'' which is generally the Physician Fee Schedule (PFS). However, consistent with our policy to pay separately payable, covered outpatient drugs and biologicals acquired under the 340B Program at ASP minus 22.5 percent, rather than ASP+6 percent, when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022), we finalized a policy to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in non-excepted off-campus PBDs paid under the PFS. We adopted this payment policy effective for CY 2019 and subsequent years.

We clarified in the CY 2019 OPPS/ASC proposed rule (83 FR 37125) that the 340B payment adjustment applies to drugs that are priced using either WAC or AWP, and that it has been our policy to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment since the policy was first adopted. The 340B payment adjustment for WAC-priced drugs is WAC minus 22.5 percent. 340B-acquired drugs that are priced using AWP are paid an adjusted amount of 69.46 percent of AWP. The 69.46 percent of AWP is calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we apply the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which is similar to either ASP minus 22.5 percent or WAC minus 22.5 percent.

As discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), to effectuate the payment adjustment for 340B-acquired drugs, we implemented modifier ''JG'', effective January 1, 2018. Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as critical access hospitals), or excepted from the 340B drug payment policy for CY 2018, were required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals were excepted from the 340B payment adjustment. These hospitals were required to report informational modifier ''TB'' for 340B-acquired drugs, and continue to be paid ASP+6 percent. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and use of modifiers ''JG'' and ''TB''.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58981), we continued the Medicare 340B payment policies that were implemented in CY 2018 and adopted a policy to pay for nonpass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than of the reference product's ASP. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321), we continued the 340B policies that were implemented in CY 2018 and CY 2019.

Our CY 2018 and 2019 OPPS payment policies for 340B-acquired drugs have been the subject of ongoing litigation. On December 27, 2018, in the case of *American Hospital Association, et al.* v. *Azar, et al.,* the district court concluded in the context of reimbursement requests for CY 2018 that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22.5 percent for that year.[178] In that same decision, the district court recognized the ''havoc that piecemeal review of OPPS payment could bring about' in light of the budget neutrality requirement,'' and ordered supplemental briefing on the appropriate remedy.[179] On May 6, 2019, after briefing on remedy, the district court issued an opinion that reiterated that the 2018 rate reduction exceeded the Secretary's authority, and declared that the rate reduction for 2019 (which had been finalized since the Court's initial order was entered) also exceeded his authority.[180] Rather than ordering HHS to pay plaintiffs their alleged underpayments, however, the district court recognized that crafting a remedy is ''no easy task, given Medicare's complexity,'' [181] and initially remanded the issue to HHS to devise an appropriate remedy while also retaining jurisdiction. The district court acknowledged that ''if the Secretary were to retroactively raise the 2018 and 2019 340B rates, budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services.'' [182] ''And because HHS has already processed claims under the previous rates, the Secretary would potentially be required to recoup certain payments made to providers; an expensive and time-consuming prospect.'' [183]

We respectfully disagreed with the district court's understanding of the scope of the Secretary's adjustment authority. On July 10, 2019, the district court entered final judgment. The agency appealed to the D.C. Circuit, and on July 31, 2020, the court entered an opinion reversing the district court's judgment in this matter. Following the D.C. Circuit's decision, appellees' petition for panel rehearing and petition for rehearing en banc were denied on October 16, 2020. In January of 2021, appellees petitioned the United States Supreme Court for a writ of certiorari. On July 2, 2021, the Court granted the petition.

Before the D.C. Circuit upheld our authority to pay ASP minus 22.5 percent, we stated in the CY 2020 OPPS/ASC final rule with comment period that we were taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal. Notably, after the CY 2020 OPPS/ASC proposed rule was issued, we announced in the **Federal Register** (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for certain quarters in CY 2018 and 2019. We stated that such survey data may be used in setting the Medicare payment amount for drugs acquired by 340B hospitals for cost years going forward, and also may be used to devise a remedy for prior years if the district court's ruling was upheld on appeal. The district court itself acknowledged that CMS may base the Medicare payment amount on average acquisition cost when survey data are available.[184] No 340B hospital disputed in the rulemakings for CY 2018 and 2019 that the ASP minus 22.5 percent formula was a conservative adjustment that represented the minimum discount that hospitals receive for drugs acquired through the 340B program, which is significant because 340B hospitals have internal data regarding their own drug acquisition costs. We stated in the CY 2020 OPPS/ASC final rule with comment period that we thus

[178] *American Hosp. Ass'n, et al.* v. *Azar, et al.,* No. 1:18–cv–2084 (D.D.C. Dec. 27, 2018).

[179] *Id.* at 35 (quoting *Amgen, Inc.* v. *Smith,* 357 F.3d 103, 112 (D.C. Cir. 2004) (citations omitted)).

[180] *See* May 6, 2019 Memorandum Opinion, Granting in Part Plaintiffs' Motion for a Permanent Injunction; Remanding the 2018 and 2019 OPPS Rules to HHS at 10–12.

[181] *Id.* at 13.

[182] *Id.* at 19.

[183] *Id.* (citing Declaration of Elizabeth Richter).

[184] *See American Hosp. Assoc.* v. *Azar,* 348 F. Supp. 3d 62, 82 (D.D.C. 2018).

anticipated that survey data collected for CY 2018 and 2019 would confirm that the ASP minus 22.5 percent rate is a conservative amount that overcompensates covered entity hospitals for drugs acquired under the 340B program. We also explained that a remedy that relies on such survey data could avoid the complexities referenced in the district court's opinion. For a complete discussion of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Outpatient Drugs, we refer readers to the CY 2021 OPPS/ASC proposed rule (85 FR 48882 through 48891) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055).

We proposed a payment rate for 340B drugs of ASP minus 28.7 percent based on survey data, and also proposed in the alternative that the agency could continue its current policy of paying ASP minus 22.5 percent for CY 2021. We explained that we adopted the OPPS 340B payment policy based on the average minimum discount for 340B-acquired drugs being approximately ASP minus 22.5 percent. The estimated discount was based on a MedPAC analysis identifying 22.5 percent as a conservative minimum discount that 340B entities receive when they purchase drugs under the 340B program, which we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52496). We emphasized that we continue to believe that ASP minus 22.5 percent is an appropriate payment rate for 340B-acquired drugs under the authority of section 1833(t)(14)(A)(iii)(II) for the reasons we stated when we adopted this policy in CY 2018 (82 FR 59216). We pointed out that on July 31, 2020, the D.C. Circuit reversed the decision of the district court, holding that this interpretation of the statute was reasonable. Therefore, we also proposed in the alternative that the agency could continue the current Medicare payment policy for CY 2021. If adopted, we stated that this proposed policy would continue the current Medicare payment policy for CY 2021.

Based on feedback from stakeholders, we stated that we believed maintaining the current payment policy of paying ASP minus 22.5 percent for 340B drugs was appropriate in order to maintain consistent and reliable payment for these drugs both for the remainder of the PHE, and after its conclusion, to give hospitals increased certainty as to payments for these drugs. We explained that continuing our current policy also gives us more time to conduct further analysis of hospital survey data for potential future use for 340B drug payment. We also noted that any changes to the current 340B payment policy would be adopted through public notice and comment rulemaking.

Finally, we stated that while we believe our methods to conduct the 340B Drug Acquisition Cost Survey, as well as the methodology we used to calculate the proposed average or typical discount received by 340B entities on 340B drugs, are valid, we nonetheless recognize the comments that we received from stakeholders. Utilization of the survey data is complex, and we emphasized that we wish to continue to evaluate how to balance and weigh the use of the survey data, the necessary adjustments to the data, and the weighting and incorporation of ceiling prices—all to determine how best to take the relevant factors into account for potentially using the survey to set Medicare OPPS drug payment policy. We stated that we would continue to assess commenters' feedback as we explore whether survey data should be considered hospital acquisition cost data for purposes of paying for drugs acquired under section 1833(t)(14)(A)(iii)(I) of the Act.

c. CY 2022 Proposed 340B Drug Payment Policy

For CY 2022, we proposed to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs and biologicals, including when furnished in nonexcepted off-campus PBDs paid under the PFS. We proposed, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, to pay for separately payable Medicare Part B drugs and biologicals (assigned status indicator ''K''), other than vaccines and drugs on pass-through status, that are acquired through the 340B Program at ASP minus 22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. We proposed to continue our current policy for calculating payment for 340B-acquired biosimilars, which is discussed in section V.B.2.c. of the CY 2019 OPPS/ASC final rule with comment period, and would continue the policy we finalized in CY 2019 to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs paid under the PFS.

We also proposed to continue the 340B payment adjustment for WAC-priced drugs, which is WAC minus 22.5 percent. 340B-acquired drugs that are priced using AWP would continue to be paid an adjusted amount of 69.46 percent of AWP. Additionally, we proposed to continue to exempt rural sole community hospitals (as described under the regulations at § 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment. We stated that these hospitals would continue to report informational modifier ''TB'' for 340B-acquired drugs, and would continue to be paid ASP+6 percent. We also explained that we may revisit our policy to exempt rural SCHs, as well as other hospital types, from the 340B drug payment reduction in future rulemaking.

We stated that we are also continuing to require hospitals to use modifiers to identify 340B-acquired drugs. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and the requirements for use of modifiers ''JG'' and ''TB''. We explained that we believe maintaining the current policy of paying ASP minus 22.5 percent for 340B drugs is appropriate given the July 31, 2020 D.C. Circuit decision, which reversed the district court's decision and held that the interpretation of the statute was reasonable when the 340B drug payment policy was implemented in CY 2018. We noted that any changes to the current 340B payment policy would be adopted through public notice and comment rulemaking.

While we believe the Secretary has discretion to propose a payment rate for 340B drugs based on the 2020 survey results, we explained that we also continue to believe that the current payment rate of ASP minus 22.5 percent represents the minimum discount that 340B covered entities receive, which more closely aligns the payment rate with the resources expended by 340B hospitals to acquire such drugs compared to a payment rate of ASP+6 percent, while also recognizing the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients. Additionally, we stated that we continue to believe it is important to provide consistency and reliable payment for these drugs both for the remainder of the PHE, and after its conclusion, to give hospitals increased certainty as to payments for these drugs.

d. Comments on the Proposed CY 2022 340B Payment Policy

Comment: Several commenters, including a hospital association, pharmaceutical research and manufacturing companies, and a community oncology association,

supported the current OPPS payment policy for 340B-acquired drugs. They believed that approximating payment based on acquisition costs is appropriate; however, they also recommended reform to the 340B program itself. Some of these commenters believed the policy would continue to address the inappropriate growth of the 340B Program, stem physician practice consolidation with hospitals, and preserve patient access to community-based care.

Response: We thank the commenters for their support of our 340B payment policies. We note that comments related to the reform of the 340B program are outside of the scope of this final rule and we also note that the 340B program is administered by the Health Resources and Services Administration, not CMS; however, we thank commenters for their input.

Comment: A commenter inquired if the 340B drug payment policy applies to therapeutic radiopharmaceuticals that are paid based on the mean unit cost data, stating that it would be inappropriate and inaccurate to apply the 22.5 percent reduction to these payment amounts. Another commenter opposed the 340B drug payment policy specifically for therapeutic radiopharmaceuticals, citing the unique cost structure of radiopharmaceuticals. Another commenter requested a similar-product specific exemption for Chimeric Antigen Receptor T-cell (CAR T-cell) therapy when purchased through the 340B program.

Response: The 340B drug payment policy applies to OPPS separately payable drugs (status indicator ''K'') purchased through the 340B drug program, which include therapeutic radiopharmaceuticals when these products are acquired through the 340B drug program. The classes of drugs exempted from the policy are vaccines (status indicator ''L'' or ''M''), and drugs with transitional pass-through payment status (status indicator ''G''). We note that the drug cost methodology has no impact on the application of the 340B discount. As we noted above, our policy applies to all drugs purchased through the 340B drug program except for vaccines and drugs with transitional pass-through payment status. While we acknowledge that radiopharmaceuticals necessitate special handling, we note that there are other drug classes that also necessitate special handling under the 340B program. Therefore, we disagree with the commenter that therapeutic radiopharmaceuticals purchased through the 340B drug program should qualify for an exemption from application of the payment adjustment. We note that, under the OPPS, the 340B payment adjustment is ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP. We reiterate, these payment rates are based on the minimum average discount for products purchased through the 340B program, with the actual acquisition costs likely being much lower.

Comment: Some commenters had concerns that new biosimilars on pass-through status would have a competitive advantage over their reference product as a result of the disparity in OPPS payment for these products when a biosimilar has pass-through status. Commenters believed the disparity resulting from the combined 340B drug payment and pass-through policies would advantage biosimilars receiving pass-through payment if the applicable reference product is acquired under the 340B program and not receiving pass-through payment. The commenters believe the disparity would lead to inappropriate prescribing inconsistent with clinical guidelines and/or standards of care.

Response: We disagree with commenters that the current payment policy would unfairly place reference products at a competitive disadvantage relative to their applicable biosimilars. We believe the continuation of our current biosimilar policy will allow for appropriate payment and access to these important treatments. As noted in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86043), we do not believe that the biosimilars' temporary payments provided by pass-through status will create the substantial competitive advantage that commenters described. We note that the advantage of pass-through payment exists under the current 340B policy that includes both new drugs and biosimilars. We also note we are continuing the policy from previous years regarding biosimilars and 340B payment. Please see section V.B.2.C. of this final rule with comment period for additional discussion regarding biosimilars and section V.A.1. for additional discussion on drug pass-through payments. We note that the advantage of pass-through payment exists under the current 340B policy that includes both new drugs and biosimilars. We are continuing the policy from previous years regarding payment for biosimilars acquired under the 340B program.

Comment: Several commenters disagreed that ASP minus 22.5 was a conservative adjustment that represented the minimum discount that hospitals receive when they acquire drugs through the 340B program. They contended that they are losing money when dispensing certain drugs as the price paid by CMS is significantly lower than the price paid by the entity.

Response: We thank the commenters for their feedback. The 22.5 percent discount off of ASP is a conservative minimum discount for products acquired under the 340B program based on a 2015 MedPAC analysis, which we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52496). Our 2020 Hospital Acquisition Cost Survey for 340B-Acquired SCODs has shown the average discount to be about 34.7 percent. As noted in the 2021 OPPS/ASC final rule with comment period (85 FR 86045), the 2020 Hospital Acquisition Cost Survey for 340B-Acquired SCODS incorporated the 340B ceiling prices for hospitals that did not affirmatively respond to the survey and may have skewed the average discount determined based on survey results (34.7 percent off of ASP) towards the *minimum* average discount (that is, the ceiling price) that a 340B hospital would receive on a drug. Since the ceiling price is the maximum amount covered entities may permissibly be required to pay for a drug under section 340B(a)(1) of the Public Health Service Act, we would not expect any 340B hospital to have acquisition costs for any acquired drug that are greater than ASP minus 22.5 percent. Therefore, we disagree that covered entities are, on average, losing money under the current 340B drug payment policy of ASP minus 22.5 percent for drugs purchased through the 340B drug program.

Comment: Several commenters requested that we make our 340B exemptions policy permanent. Additionally, commenters asked CMS to extend the exemption to urban SCHs, Medicare Dependent Hospitals, Rural Referral Centers.

Response: We thank commenters for their recommendations. At this time, we do not believe it is appropriate to revise our 340B exemptions policy and believe we should maintain our current policy for CY 2022. Nonetheless, we will take these comments into consideration for future rulemaking.

Comment: Several commenters stated that CMS has not provided sufficient analysis for the continuation of the 340B payment policy, expressing their belief that CMS has not considered changes in utilization or volume for hospitals that are actively participating in the 340B program since the implementation of the policy. They further noted that CMS has not analyzed the impact of the prior year's reimbursement changes for drugs acquired under the 340B program for the affected hospitals. They contended

that CMS has not provided evidence that the payment policy remains budget neutral by recalculating the policy's impact to make sure the conversion factor is properly adjusted over time to reflect changes in inflation or 340B drug utilization.

Response: In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we implemented the 340B drug payment policy and adjusted the payment rate for separately payable drugs and biologicals (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program. This adjustment changed the payment rate from ASP+6 percent to ASP minus 22.5 percent for drugs subject to this policy. In that rule, we stated that our goal was to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs. We believe the current 340B drug payment policy reflects the average minimum discount that 340B participating hospitals receive for drugs acquired under the 340B Program, and we believe it is inappropriate for Medicare to subsidize other programs through Medicare payments for separately payable drugs. We note the data collected in our 2020 Hospital Acquisition Cost Survey for 340B-acquired SCODs found the average 340B program drug discount to be 34.7 percent.

With respect to OPPS budget neutrality and the conversion factor, OPPS budget neutrality is generally developed on a prospective basis by isolating the effect of any changes in payment policy or data under the prospective OPPS with all other factors held constant. We note that since the CY 2018 implementation of the 340B drug payment policy in which we developed a budget neutrality adjustment for the policy, the adjusted percentage payment has remained at ASP minus 22.5 percent. As a result, while some of the claims may change based on drug payment and billing, as indicated by the ''JG'' modifier, these drugs, including their utilization and expected payments, would be included as part of the broader budget neutrality adjustments, but collectively they would not have a separate budget neutrality adjustment specifically for the 340B drug payment policy. We note that in the rules in which we proposed to establish or modify the adjustment, we have included in the impact analysis the estimated effects on different categories of providers based on the policy. Finally, we note that we monitor the payment and utilization patterns associated with this adjustment and for drug spending more broadly, and will continue to do so.

Comment: Several commenters called on CMS to suspend the current 340B drug payment policy and restore the 340B drug and biological payment rate to the statutory ASP+6 percent until the litigation is resolved in the U.S. Supreme Court. Other commenters recommended CMS postpone any changes to the 340B drug payment policy until the court case has concluded. Others recommended CMS suspend the policy amid the COVID–19 Public Health Emergency (PHE).

Response: We acknowledge that the issue of the Secretary's authority to adjust the 340B drug payment rate is subject to litigation before the U.S. Supreme Court. As explained at prior stages of the litigation, we believe that the suit now before the Court is precluded by 1833(t)(12), and, in the alternative, that our 340B drug payment policy is within the statutory authority under 1833(t)(14)(A), which was confirmed by the D.C. Circuit. While the litigation involving this policy is pending, we believe maintaining the current payment policy for CY 2022 would be appropriate in order to maintain consistent and reliable payment. Regarding payment during the COVID–19 PHE, we believe maintaining consistent payment is important; therefore, we are maintaining our proposed policy. We note that any changes to this payment policy would be adopted through notice and comment rulemaking.

Comment: Many commenters opposed the CY 2022 proposal to pay for drugs acquired under the 340B program at the payment rate of ASP minus 22.5 percent. These commenters urged CMS to withdraw its proposed policy and contended that the policy was an unlawful application of the CMS's authority.

Many commenters opposed the current 340B policy and argued that it redistributes resources designated for safety net hospitals to subsidize non-340B or private hospitals because the payment reduction is budget neutral. The commenters requested that CMS end its policy of paying for drugs obtained through the 340B program at ASP minus 22.5 percent and restore the statutory default payment rate of ASP+6 percent.

Many commenters also alleged that private pharmacy benefit managers and third-party payers are citing Medicare's payment reduction to justify implementing similar policies that provide lower reimbursement for 340B drugs compared to non-340B drugs.

Response: We respectfully disagree with the commenters' assertions that our 340B drug payment policy is illegal or an unlawful application of the law. We disagree with commenters that the OPPS 340B payment policy has taken away resources designated for safety net hospitals and our internal analyses have not demonstrated any issues related to access of separately payable drugs as a result of the implementation of this policy. As discussed in this section of the CY 2022 final rule with comment period, the D.C. Circuit has confirmed that our 340B drug payment policy is within our authority in section 1833(t)(14) of the Act.

We note that CMS does not control policies created by private pharmacy benefit managers and third-party payers regarding payment for 340B drugs compared to non-340B drugs.

After reviewing the public comments for CY 2022, we are finalizing our proposal, without modification, to pay ASP minus 22.5 percent for 340B-acquired drugs, including when furnished in nonexcepted off-campus PBDs paid under the PFS. Our finalized proposal continues the 340B Program policies that were implemented in CY 2018 with the exception of the way we are calculating payment for 340B-acquired biosimilars, which is discussed in section V.B.2.c. of the CY 2019 OPPS/ASC final rule with comment period, and would continue the policy we finalized in CY 2019 to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs paid under the PFS.

We believe that the current payment rate of ASP minus 22.5 percent represents the minimum discount that 340B covered entities receive, which more closely aligns the payment rate with the resources expended by 340B hospitals to acquire such drugs compared to a payment rate of ASP+6 percent, while also recognizing the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients. Additionally, we continue to believe it is important to provide consistent and reliable payment for these drugs both for the remainder of the PHE, and after its conclusion, to give hospitals increased certainty as to payments for these drugs. We note that any changes to this payment policy would be adopted through notice and comment rulemaking.

7. High Cost/Low Cost Threshold for Packaged Skin Substitutes

a. Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package skin substitutes, we also finalized a methodology that divides the skin substitutes into a high cost group and a low cost group, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933).

Skin substitutes assigned to the high cost group are described by HCPCS codes 15271 through 15278. Skin substitutes assigned to the low cost group are described by HCPCS codes C5271 through C5278. Geometric mean costs for the various procedures are calculated using only claims for the skin substitutes that are assigned to each group. Specifically, claims billed with HCPCS code 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high cost group, and claims billed with HCPCS code C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low cost group (78 FR 74935).

Each of the HCPCS codes described earlier are assigned to one of the following three skin procedure APCs according to the geometric mean cost for the code: APC 5053 (Level 3 Skin Procedures): HCPCS codes C5271, C5275, and C5277; APC 5054 (Level 4 Skin Procedures): HCPCS codes C5273, 15271, 15275, and 15277; or APC 5055 (Level 5 Skin Procedures): HCPCS code 15273. In CY 2021, the payment rate for APC 5053 (Level 3 Skin Procedures) was $524.17, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,715.36, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $3,522.15. This information also is available in Addenda A and B of the CY 2021 OPPS/ASC final rule with comment period, as issued with the final rule correction notice (86 FR 11428) (the correction notice and corrected Addenda A and B are available via the internet on the CMS website).

We have continued the high cost/low cost categories policy since CY 2014, and we proposed to continue it for CY 2022. Under the current policy, skin substitutes in the high cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high cost group or the low cost group, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high cost/low cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434 through 70435). Beginning in CY 2016 and in subsequent years, we adopted a policy where we determined the high cost/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. We assigned each skin substitute that exceeded either the MUC threshold or the PDC threshold to the high cost group. In addition, we assigned any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group (85 FR 86059).

However, some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year using the methodology developed in CY 2016. The fluctuation in the thresholds may result in the reassignment of several skin substitutes from the high cost group to the low cost group which, under current payment rates, can be a difference of over $1,000 in the payment amount for the same procedure. In addition, these stakeholders were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute stakeholders requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and also requested that CMS consider whether it might be appropriate to establish a new cost group in between the low cost group and the high cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

We share the goal of promoting payment stability for skin substitute products and their related procedures as price stability allows hospitals using such products to more easily anticipate future payments associated with these products. We have attempted to limit year-to-year shifts for skin substitute products between the high cost and low cost groups through multiple initiatives implemented since CY 2014, including: Establishing separate skin substitute application procedure codes for low-cost skin substitutes (78 FR 74935); using a skin substitute's MUC calculated from outpatient hospital claims data instead of an average of ASP+6 percent as the primary methodology to assign products to the high cost or low cost group (79 FR 66883); and establishing the PDC threshold as an alternate methodology to assign a skin substitute to the high cost group (80 FR 70434 through 70435).

To allow additional time to evaluate concerns and suggestions from stakeholders about the volatility of the MUC and PDC thresholds, in the CY 2018 OPPS/ASC proposed rule (82 FR 33627), we proposed that a skin substitute that was assigned to the high cost group for CY 2017 would be assigned to the high cost group for CY 2018, even if it did not exceed the CY 2018 MUC or PDC thresholds. We finalized this policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347). We stated in the CY 2018 OPPS/ASC proposed rule that the goal of our proposal to retain the same skin substitute cost group assignments in CY 2018 as in CY 2017 was to maintain similar levels of payment for skin substitute products for CY 2018 while we study our skin substitute payment methodology to determine whether refinements to the existing policies are consistent with our policy goal of providing payment stability for skin substitutes.

We stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347) that we would continue to study issues related to the payment of skin substitutes and take these comments into consideration for future rulemaking. We received many responses to our request for comments in the CY 2018 OPPS/ASC proposed rule about possible refinements to the existing payment methodology for skin substitutes that would be consistent with our policy goal of providing payment stability for these products. In addition, several stakeholders have made us aware of additional concerns and recommendations since the release of the CY 2018 OPPS/ASC final rule with comment period. As discussed in

the CY 2019 OPPS/ASC final rule with comment period (83 FR 58967 through 58968), we identified four potential methodologies that have been raised to us that we encouraged the public to review and provide comments on. We stated in the CY 2019 OPPS/ASC final rule with comment period that we were especially interested in any specific feedback on policy concerns with any of the options presented as they relate to skin substitutes with differing per day or per episode costs and sizes and other factors that may differ among the dozens of skin substitutes currently on the market.

For CY 2020, we sought more extensive comments on the two policy ideas that generated the most comment from the CY 2019 comment solicitation. One of the ideas was to establish a payment episode between 4 to 12 weeks where a lump-sum payment would be made to cover all of the care services needed to treat the wound. There would be options for either a complexity adjustment or outlier payments for wounds that require a large amount of resources to treat. The other policy idea would be to eliminate the high cost and low cost categories for skin substitutes and have only one payment category and set of procedure codes for the application of all graft skin substitute products. Please refer to the CY 2019 OPPS final rule (83 FR 58967 to 58968) and the CY 2020 OPPS final rule (84 FR 61328 to 61331) for a detailed summary and discussion of the comments we received in response to these comment solicitations. We are continuing to consider the comments we received in response to these comment solicitations from CY 2019 and CY 2020.

Comment: Multiple commenters provided suggestions on changes to the payment methodology for graft skin substitute payment policy for future rulemaking.

Response: We appreciate the additional advice regarding possible changes to the payment methodology for graft skin substitute products, and we will consider this information as a part of future rulemaking.

b. Packaged Skin Substitutes for CY 2022

For CY 2022, consistent with our policy since CY 2016, we proposed to continue to determine the high cost/low cost status for each skin substitute product based on either a product's geometric MUC exceeding the geometric MUC threshold or the product's PDC (the total units of a skin substitute multiplied by the MUC and divided by the total number of days) exceeding the PDC threshold. Consistent with the methodology as established in the CY 2014 OPPS/ASC through CY 2018 OPPS/ASC final rules with comment period, we analyzed CY 2019 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The proposed CY 2022 MUC threshold is $48 per cm^2 (rounded to the nearest $1) and the proposed CY 2022 PDC threshold is $949 (rounded to the nearest $1). We also proposed that our definition of skin substitutes includes synthetic skin substitute products in addition to biological skin substitute products as described in section V.B.7. (86 FR 42137 through 42143) of the CY 2022 OPPS/ASC proposed rule. We also want to clarify that the availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

For CY 2022, as we did for CY 2021, we proposed to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, we proposed to assign any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group. For CY 2022, we proposed that any skin substitute product that was assigned to the high cost group in CY 2021 would be assigned to the high cost group for CY 2022, regardless of whether it exceeds or falls below the CY 2022 MUC or PDC threshold. This policy was established in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59346 through 59348).

For CY 2022, we proposed to continue to assign skin substitutes with pass-through payment status to the high cost category. We proposed to assign skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC to either the high cost or low cost category based on the product's ASP+6 percent payment rate as compared to the MUC threshold. If ASP is not available, we proposed to use WAC+3 percent to assign a product to either the high cost or low cost category. Finally, if neither ASP nor WAC is available, we proposed to use 95 percent of AWP to assign a skin substitute to either the high cost or low cost category. We proposed to continue to use WAC+3 percent instead of WAC+6 percent to conform to our proposed policy described in section V.B.2.b of the CY 2022 OPPS/ASC proposed rule (86 FR 42132) to establish a payment rate of WAC+3 percent for separately payable drugs and biologicals that do not have ASP data available. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2022 MUC and PDC thresholds. We also proposed to continue to include synthetic products in addition to biological products in our description of skin substitutes. For a discussion of our existing policy under which we assign skin substitutes without pricing information to the low cost category until pricing information is available, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70436). For a discussion of how we determined that synthetic skin graft sheet products can be reported with graft skin substitute procedure codes, we refer readers to the CY 2021 OPPS/ASC final rule (85 FR 86064 to 86067).

Comment: The HOP Panel recommended and several commenters supported ending the packaging of the graft skin substitute add-on codes (CPT codes 15272, 15274, 15276, and 15278; HCPCS codes C5272, C5274, C5276, and C5278). The HOP Panel and the commenters request that these codes be assigned to APCs that reflect the estimated costs of these service codes. Commenters claim that packaging the graft skin substitute add-on codes eliminates the variation of payment for wound care treatment based on the size of the wound. They assert that providers are discouraged from treating wounds between 26 and 99 cm^2 and over 100 cm^2 in the outpatient hospital setting because of the financial losses they experience to provide such care. Commenters believe that packaging graft skin substitute add-on codes disrupts the methodology of how the American Medical Association (AMA), the organization that manages CPT service codes, intended graft skin substitute procedures to be paid.

Response: We do not believe the recommendation of the HOP Panel and the commenters is appropriate for paying for graft skin substitutes under the OPPS. The OPPS is a prospective payment system and not a fee-for-service payment system. That means that we generally attempt to make one payment for all of the services billed with the primary medical procedure, including add-on procedures such as

the ones described by CPT codes 15272, 15274, 15276, and 15278, and HCPCS codes C5272, C5274, C5276, and C5278.

More specifically, we calculate the OPPS payment rate by first calculating the geometric mean cost of the procedure. This calculation includes claims for individual services that used a lower level of resources and claims for individual services that used a higher level of resources. The resulting geometric mean cost will reflect the median service cost for a given medical procedure. Next, we group the medical procedure with other medical procedures with clinical and resource similarity in an APC and calculate the geometric mean of these related procedures to generate a base payment rate for all procedures assigned to the APC.

A prospective payment system like the OPPS is designed to pay providers the geometric mean cost of the primary service they provide, and such a system encourages efficiencies and cost-savings in the administration of health care. However, a prospective payment system is not intended to discourage providers from rendering medically-necessary to patients. For example, it's possible that a provider could experience a financial loss when they perform a service where a patient receives 85 cm^2 of a graft skin substitute product, but that same provider could see a financial gain when the next patient receives a skin graft where only 10 cm^2 of product is used. Paying separately for add-on codes in a prospective payment system defeats the goals of such a payment system. If providers are paid at cost or nearly at cost for each individual service they render, there is no incentive for them to control costs. Add-on codes should be packaged with the primary medical service to be able to establish a median payment rate that gives providers incentives to keep their costs in line with typical providers throughout the Medicare program. The need for cost efficiencies in the application of graft skin substitutes to treat wounds is no different than need for cost efficiencies in other procedures administered in the outpatient hospital setting. Therefore, add-on codes, including the add-on codes for the administration of graft skin substitutes must remain packaged to maintain the integrity of the OPPS.

Comment: The HOP Panel recommended and several commenters support ensuring that the payment rate of graft skin substitute procedures be the same no matter where on the body the graft skin substitute product is applied to the patient. There are four graft skin substitute application procedures for high cost skin substitute products (CPT codes 15271, 15273, 15275, and 15277) and a similar four graft skin substitute applications for low cost skin substitute products (HCPCS codes C5272, C5274, C5276, and C5278). The reason there are four application service codes is that there are different service codes for applying graft skin substitutes to children and infants as compared to adults and there are different service codes for applying graft skin substitutes to the trunk, arms, and legs as compared to the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, fingers, and toes. Commenters claim that the cost to apply graft skin substitute products does not depend on the location of the wound because the same amount of product is used on the wound and the same clinical resources are used to treat the wound independent of the location of the wound.

Response: We appreciate commenters concerns and note that that current codes describing the application of high and low cost graft skin substitutes for adults (CPT codes 15271 and 15275, and HCPCS codes C5272 and C5276) have been assigned the same APC (5054). Because they are currently included in the same APC, OPPS payment for them is the same, and this payment policy is consistent with the recommendation from the HOP Panel and other commenters. We note that the codes describing the application of high and low cost products for *children and infants* in the trunk, arms, and legs (CPT code 15273 or HCPCS code C5274) have been assigned to a lower-paying APC (APC 5054) than the APC assignment for the application of high and low cost graft skin substitute products for children in the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hand, feet, fingers, and toes—CPT code 15277 or HCPCS code C5277, which are assigned to APC 5055. These APCs have different payment rates. We note that these services—the application of skin substitutes for children—are fairly low volume services in the OPPS because Medicare beneficiaries tend to be older. In addition, the differences in costs that have determined APC assignments for these services for children have been supported by historical cost data. We also note that none of these service codes are in violation of the 2-times rule. While we do not believe we should change the APC assignments for these services at this time, we are interested in additional feedback on this issue, including whether we should revaluate APC assignments for the application of skin substitutes for children in the future.

Comment: One commenter did not support our proposal to assign graft skin substitute products to a high cost or a low cost group based on if the MUC or PDC of a product exceeds a weighted average of either the MUC or PDC of all graft skin substitute products. The commenter believes the current two-tier system provides incentives for providers to use higher-cost graft skin substitute products instead of lower-cost products that have similar efficacy to the higher-cost products. The commenter supports a payment system where the high cost and low cost groups have been eliminated. The commenter believes geometric mean payment rate for each graft skin substitute application service code would be calculated using all of the separately paid claims for a given code without consideration to the mean unit cost of the graft skin substitute product used in the service. The commenter believes this approach would reduce spending on graft skin substitute procedures by encouraging the use of lower-cost graft skin substitute products and will reduce administration burden for providers as they only need to use one set of product application codes.

Response: As we explained in the CY 2014 OPPS/ASC final rule (78 FR 74933), the graft skin substitute procedures described by CPT codes 15271 through 15278 are clinically homogeneous, but there is resource heterogeneity between different skin substitute products with the cost per cm^2 ranging from under $10 per cm^2 to over $200 per cm^2. As we discussed in prior rules, establishing high cost and low cost groups for skin substitutes makes the payment for these products more homogeneous and reduces the risk of excessive overpayment or underpayment to a provider when a skin substitute product is used. However, we appreciate the commenter's proposal and note that establishing a payment policy in which with only one set of product application service codes may have other benefits, such as simplifying coding and payments for these procedures and products, and we may explore these concepts in future rulemaking.

Comment: Two commenters supported our proposal to continue to assign skin substitutes to the low cost or high cost group. Commenters also supported our proposal that any skin substitute product that was assigned to the high cost group in CY 2020 would be assigned to the high cost group for CY 2021, regardless of whether it exceeds or falls below the CY 2021 MUC or PDC threshold.

Response: We appreciate the support of the commenters for our proposals.

Comment: Two commenters supported our inclusion of synthetic products in our definition of skin substitute products.

Response: We appreciate the support of the commenters.

Comment: One commenter requested that CMS no longer use the term ''skin substitutes'' to describe products that do not function like human skin that is grafted onto a wound and are not substitutes for skin grafts, but do aid in wound healing by stimulating the patient to regenerate lost tissue. Instead, the commenters request that we use the term ''cellular and/or tissue based products for skin wounds'' that is abbreviated ''CTPs''.

Response: We appreciate the suggestion by the commenter, but we do not believe it is appropriate at this time to end our use of the term ''skin substitute.'' Notably, the CPT and HCPCS codes used to report graft procedures using cellular and tissue based products to heal skin wounds, CPT codes 15271 through 15278 and HCPCS codes C5271 through C5278, use the term ''skin substitute'' in the descriptor. We feel that we should use terminology that reflects the service descriptors that are reported in the OPPS. Also, we believe the term ''skin substitute'' is well-understood by providers and industry stakeholders.

Comment: Two commenters wanted us to confirm that our proposed rule language that encourages manufacturers of HCT/Ps to consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271 applied only to those HCT/Ps that do not have either an FDA 510(k) clearance, premarket approval (PMA), or biologic license application (BLA) approval. These commenters are supportive of the policy as long as no consultation or determination is required for HCT/Ps with either a 510(k) clearance, a PMA, or a BLA approval.

Response: We can confirm that our suggestion for manufacturers of HCT/Ps to consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271 does apply only to those HCT/Ps that do not have either a 510(k) clearance, a PMA, or a BLA approval from FDA.

Comment: Multiple commenters stated that HCPCS code C1849, which is used to report synthetic graft skin substitute products, should be assigned to the low cost skin substitute group by default, similar to how we pay for HCPCS code Q4100 (Skin substitute, not otherwise specified), which is used to report multiple biological skin substitute products that do not have product-specific HCPCS codes. Commenters also expressed concerns that synthetic graft skin substitute products that should receive payment through the low cost skin substitute group would instead receive payment in the high cost skin substitute group and increase overall graft skin substitute costs for Medicare.

Response: We were aware of one synthetic graft skin substitute product that was described by HCPCS code C1849 when the code was established in July 2020. The manufacturer provided pricing data that showed the cost of the product is above the MUC threshold for graft skin substitute products and therefore HCPCS code C1849 should be assigned to the high cost skin substitute group. We note that we used pricing data to assign HCPCS code C1849 to the high cost group, and the assignment of HCPCS code C1849 to the high cost skin substitute group was not automatic. As more synthetic graft skin substitute products are identified, we will use their pricing data to calculate an average price for the products described by HCPCS code C1849 and compare that average price to the overall MUC threshold to determine whether HCPCS code C1849 should be assigned to the high cost or low cost skin substitute group.

Comment: One commenter noted that CMS previously assigned HCPCS code Q4117 (Hyalomatrix, per square centimeter) to a product considered a synthetic skin substitute which demonstrates that synthetic skin substitutes can function within the current coding under both the PFS and OPPS frameworks. The commenter stated that it would be better for CMS to judiciously assign HCPCS codes to synthetic products that meet these application requirements.

Response: We will take this suggestion into consideration for future rulemaking as we continue our work to address payment for all skin substitutes across settings, taking into account the intersection between biological, bioengineered, and synthetic components of these products. We also plan to further evaluate the characteristics of products with an existing Q-code for future rulemaking.

Comment: One commenter, the manufacturer, has requested that HCPCS codes Q4122 (Dermacell, per square centimeter) and Q4150 (Allowrap ds or dry, per square centimeter) continue to be assigned to the high-cost skin substitute group.

Response: HCPCS codes Q4122 and Q4150 were both assigned to the high cost group in CY 2021 and also were proposed to be assigned to the high-cost group for CY 2022. Any skin substitute assigned to the high cost group in CY 2021 will continue to be assigned to the high cost group in CY 2022 even if the MUC and PDC for the skin substitute product is below the overall MUC and PDC thresholds for all skin substitute products. Accordingly, we are finalizing our proposal to assign HCPCS codes Q4122 and Q4150 to the high-cost group in CY 2022.

After consideration of the public comments we received, we are finalizing our proposal to assign a skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group, unless the product was assigned to the high cost group in CY 2021, in which case we would assign the product to the high cost group for CY 2022, regardless of whether it exceeds the CY 2022 MUC or PDC threshold. We are also finalizing our proposal to assign to the high cost group any skin substitute product that exceeds the CY 2022 MUC or PDC thresholds and assign to the low cost group any skin substitute product that does not exceed the CY 2021 MUC or PDC thresholds and was not assigned to the high cost group in CY 2021. We are finalizing our proposal to continue to use payment methodologies, including ASP+6 percent and 95 percent of AWP, for skin substitute products that have pricing information but do not have claims data to determine if their costs exceed the CY 2022 MUC. In addition, we are finalizing our proposal to continue to use WAC+3 percent instead of WAC+6 percent for skin substitute products that do not have ASP pricing information or claims data to determine if those products' costs exceed the CY 2022 MUC. We also are finalizing our proposal to retain our established policy to assign new skin substitute products with pricing information to the low cost group. Table 42 includes the final CY 2022 cost category assignment for each skin substitute product.

BILLING CODE 4120–01–P

TABLE 42: SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2022

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Final CY 2022 High/Low Cost Assignment
C1849	Skin substitute, synthetic	High	High
C9363	Integra meshed bil wound mat	High	High*
Q4100	Skin substitute, nos	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis wound matrix	Low	Low
Q4103	Oasis burn matrix	High	High*
Q4104	Integra bmwd	High	High
Q4105	Integra drt or omnigraft	High	High
Q4106	Dermagraft	High	High
Q4107	Graftjacket	High	High
Q4108	Integra matrix	High	High*
Q4110	Primatrix	High	High*
Q4111	Gammagraft	Low	Low
Q4115	Alloskin	Low	Low
Q4116	Alloderm	High	High
Q4117	Hyalomatrix	Low	Low
Q4121	Theraskin	High	High*
Q4122	Dermacell	High	High
Q4123	Alloskin	High	High

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Final CY 2022 High/Low Cost Assignment
Q4124	Oasis tri-layer wound matrix	Low	Low
Q4126	Memoderm/derma/tranz/integup	High	High
Q4127	Talymed	High	High*
Q4128	Flexhd/allopatchhd/matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	Low	Low
Q4135	Mediskin	Low	Low
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence dryflex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High
Q4146	Tensix, 1cm	High	High
Q4147	Architect ecm px fx 1 sq cm	High	High
Q4148	Neox rt or clarix cord	High	High
Q4150	Allowrap ds or dry 1 sq cm	High	High
Q4151	Amnioband, guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Final CY 2022 High/Low Cost Assignment
Q4153	Dermavest, plurivest sq cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Neox 100 or clarix 100	High	High
Q4157	Revitalon 1 square cm	High	High*
Q4158	Kerecis omega3, per sq cm	High	High*
Q4159	Affinity 1 square cm	High	High
Q4160	Nushield 1 square cm	High	High
Q4161	Bio-connekt per square cm	High	High
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square centimeter	Low	Low
Q4167	Truskin, per square centimeter	Low	High
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per sq cm	Low	Low
Q4173	Palingen or palingen xplus	High	High
Q4175	Miroderm, per square cm	High	High
Q4176	Neopatch, per sq centimeter	High	High
Q4178	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	High	High

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Final CY 2022 High/Low Cost Assignment
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High
Q4182	Transcyte, per sq centimeter	Low	High
Q4183	Surgigraft, 1 sq cm	High	High
Q4184	Cellesta or duo per sq cm	High	High*
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	Low	High
Q4190	Artacent ac 1 sq cm	Low	High
Q4191	Restorigin 1 sq cm	Low	Low
Q4193	Coll-e-derm 1 sq cm	Low	High
Q4194	Novachor 1 sq cm	High	High*
Q4195	Puraply 1 sq cm	High	High
Q4196	Puraply am 1 sq cm	High	High
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1 sq cm	Low	High
Q4199	Cygnus matrix, per sq cm	N/A	Low
Q4200	Skin te 1 sq cm	Low	High
Q4201	Matrion 1 sq cm	Low	High

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Final CY 2022 High/Low Cost Assignment
Q4203	Derma-gide, 1 sq cm	High	High*
Q4204	Xwrap 1 sq cm	Low	Low
Q4205	Membrane graft or wrap sq cm	High	High
Q4208	Novafix per sq cm	High	High
Q4209	Surgraft per sq cm	Low	High
Q4210	Axolotl graf dualgraf sq cm	Low	Low
Q4211	Amnion bio or axobio sq cm	Low	High
Q4214	Cellesta cord per sq cm	Low	Low
Q4216	Artacent cord per sq cm	Low	Low
Q4217	Woundfix biowound plus xplus	Low	Low
Q4218	Surgicord per sq cm	Low	Low
Q4219	Surgigraft dual per sq cm	Low	High
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	Low	Low
Q4222	Progenamatrix, per sq cm	Low	High
Q4226	Myown harv prep proc sq cm	High	High
Q4227	Amniocore per sq cm	Low	High
Q4228	Bionextpatch, per sq cm	Low	Low
Q4229	Cogenex amnio memb per sq cm	Low	Low
Q4232	Corplex, per sq cm	Low	High

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Final CY 2022 High/Low Cost Assignment
Q4234	Xcellerate, per sq cm	High	High
Q4235	Amniorepair or altiply sq cm	Low	Low
Q4236	Carepatch per sq cm	Low	Low
Q4237	cryo-cord, per sq cm	Low	High
Q4238	Derm-maxx, per sq cm	Low	High
Q4239	Amnio-maxx or lite per sq cm	Low	High
Q4247	Amniotext patch, per sq cm	Low	Low
Q4248	Dermacyte Amn mem allo sq cm	Low	Low
Q4249	Amniply, per sq cm	Low	High
Q4250	AmnioAMP-MP per sq cm	Low	Low
Q4254	Novafix dl per sq cm	Low	Low
Q4255	Reguard, topical use per sq	Low	Low

* These products do not exceed either the proposed MUC or PDC threshold for CY 2022, but are assigned to the high cost group because they were assigned to the high cost group in CY 2021.

BILLING CODE 4120–01–C

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Amount of Additional Payment and Limit on Aggregate Annual Adjustment

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payment for drugs, biologicals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing a proposed estimate of pass-through spending in CY 2022 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2022. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of devices that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2021 or beginning in CY 2022. The sum of the proposed CY 2022 pass-through spending estimates for these two groups of device categories equaled the proposed total CY 2022 pass-through spending estimate for device categories with pass-through payment status. We determined the device pass-through estimated payments for each device category based on the amount of payment as required by section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with

comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the proposed rule, we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2022, we also proposed to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Our proposed estimate of drug and biological pass-through payment for CY 2022 for this group of items was $462.4 million, as discussed below, because we proposed that most non pass-through separately payable drugs and biologicals would be paid under the CY 2022 OPPS at ASP+6 percent with the exception of 340B-acquired separately payable drugs, which we proposed would be paid at ASP minus 22.5 percent, and because we proposed to pay for CY 2022 pass-through payment drugs and biologicals at ASP+6 percent, as we discuss in section V.A. of the CY 2022 OPPS/ASC proposed rule (86 FR 42116).

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products are not be separately paid. In addition, we policy-package all non pass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, drugs and biologicals that function as supplies when used in a surgical procedure, drugs and biologicals used for anesthesia, and other categories of drugs and biologicals, as discussed in section V.B.1.c. of the CY 2022 OPPS/ASC proposed rule (86 FR 42129 through 42131). We proposed that all of these policy-packaged drugs and biologicals with pass-through payment status will be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2022, less the policy-packaged drug APC offset amount described below. Our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2022 is not $0. This is because the pass-through payment amount and the fee schedule amount associated with the drug or biological will not be the same, unlike for separately payable drugs and biologicals. In section V.A.6. of the CY 2022 OPPS/ASC proposed rule (86 FR 42126 through 42127), we discuss our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we proposed to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we proposed to reduce our estimate of pass-through payments for these drugs or biologicals by the APC offset amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2022. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2021 or beginning in CY 2022. The sum of the CY 2022 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2022 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Estimate of Pass-Through Spending for CY 2022

For 2022, we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2022, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2021 (85 FR 86068). The pass-through payment percentage limit is calculated using pass-through spending estimates for devices and for drugs and biologicals.

For the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2022, there are 9 active categories for CY 2022. The active categories are described by HCPCS codes C2596, C1734, C1982, C1824, C1839, C1748, C1825, C1052, and C1062. Based on the information from the device manufacturers, we estimate that HCPCS code C2596 will cost $11.3 million in pass-through expenditures in CY 2022, HCPCS C1734 will cost $36.9 million in pass-through expenditures in CY 2022, HCPCS code C1982 will cost $116.3 million in pass-through expenditures in CY 2022, HCPCS code C1824 will cost $46 million in pass-through expenditures in CY 2022, HCPCS code C1839 will cost $500,000 in pass-through expenditures in CY 2022, HCPCS code C1748 will cost $39.1 million in pass-through expenditures in CY 2022, HCPCS code C1825 will cost $3.5 million pass-through expenditures in CY 2022, HCPCS code C1052 will cost $40 million in pass-through expenditures in CY 2022, and HCPCS code C1062 will cost $14.3 million in pass-through expenditures in CY 2022. Therefore, we proposed an estimate for the first group of devices of $307.9 million.

In estimating our proposed CY 2022 pass-through spending for device categories in the second group, we included: device categories that we assumed at the time of the development of the CY 2022 OPPS/ASC proposed rule will be newly eligible for pass-through payment in CY 2022; additional device categories that we estimated

could be approved for pass-through status after the development of the proposed rule and before January 1, 2022; and contingent projections for new device categories established in the second through fourth quarters of CY 2022. For CY 2022, we proposed to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. The proposed estimate of CY 2022 pass-through spending for this second group of device categories is $244.4 million.

We did not receive any public comments on this proposal. As stated earlier in this final rule with comment period, we are approving three devices for pass-through payment status in the CY 2022 rulemaking cycle: RECELL® Autologous Cell Harvesting Device, Shockwave C2 Coronary Intravascular Lithotripsy (IVL) catheter, and AngelMed Guardian® System. The manufacturers of these systems provided utilization and cost data that indicate the amount of spending for the devices would be approximately $18.4 million for RECELL® Autologous Cell Harvesting Device, $118.4 million for Shockwave C2 Coronary Intravascular Lithotripsy (IVL) catheter, and $5.1 million for AngelMed Guardian® System. Therefore, we are finalizing an estimate of $141.9 million for this second group of devices for CY 2022.

To estimate proposed CY 2022 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for at least one quarter in CY 2022, we proposed to use the CY 2019 Medicare hospital outpatient claims data regarding their utilization, information provided in the respective pass-through applications, other historical hospital claims data, pharmaceutical industry information, and clinical information regarding these drugs and biologicals to project the CY 2022 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2022, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for non pass-through drugs and biologicals that will be separately paid. Separately payable drugs are paid at a rate of ASP+6 percent with the exception of 340B-acquired drugs, for which we proposed to pay ASP minus 22.5 percent. Therefore, the proposed payment rate difference between the pass-through payment amount and the non pass-through payment amount is $462.4 million for this group of drugs.

Because payment for policy-packaged drugs and biologicals is packaged if the product is not paid separately due to its pass-through payment status, we proposed to include in the CY 2022 pass-through estimate of the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment, which we estimate for CY 2022 for the first group of policy-packaged drugs to be $0 since there are currently no policy-packaged drugs for which we have cost data that will be on pass-through in CY 2022.

We did not receive any public comments on our proposal. Using our methodology for this final rule with comment period, we calculated a CY 2022 spending estimate for this first group of drugs and biologicals of approximately $466.7 million based on our decision to maintain our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs.

To estimate proposed CY 2022 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of the proposed rule were newly eligible or recently became eligible for pass-through payment in CY 2022, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2022, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2022), we proposed to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2022 pass-through payment estimate. We also proposed to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2022 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $10 million.

We did not receive any public comments on our proposal. Since the release of the CY 2022 OPPS/ASC proposed rule, we have identified seven additional policy-packaged drugs in addition to the three policy-packaged drugs that had pass-through status when the proposed rule was released. Our original proposed estimate of $10 million of additional pass-through payments for the second group of drugs and biologicals did anticipate the approval of some of the additional policy-packaged drugs and biologicals with pass-through status, but not all of them. Therefore, for this final rule, we are revising our estimate of pass-through spending for the second group of drugs and biologicals to be $20 million.

We estimate for this final rule with comment period that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2022 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2022 would be approximately $936.5 million (approximately $449.8 million for device categories and approximately $486.7 million for drugs and biologicals) which represents 1.14 percent of total projected OPPS payments for CY 2022 (approximately $82 billion). Therefore, we estimate that pass-through spending in CY 2022 will not amount to 2.0 percent of total projected OPPS CY 2022 program spending. As discussed in section X.E. of the CY 2022 OPPS/ASC proposed rule (86 FR 42188 through 42190), due to the effects of the COVID–19 PHE, we proposed to generally use CY 2019 claims data instead of CY 2020 claims data to establish the CY 2022 OPPS rates and to use cost report data from the same set of cost reports originally used in CY 2021 final rule OPPS ratesetting. We stated that if our proposal to use CY 2019 data, rather than CY 2020 data, to inform CY 2022 ratesetting is finalized, we would effectively remove approximately one year of pass-through data collection time for ratesetting purposes. Therefore, for CY 2022, in section X.F. of the CY 2022 OPPS/ASC proposed rule (86 FR 42190 through 42193), we proposed to

use our equitable adjustment authority under 1833(t)(2)(E) to provide up to four quarters of separate payment for 21 drugs and biologicals whose pass-through payment status will expire on March 31, 2022, June 30, 2022, or September 30, 2022 and six drugs and biologicals and one device category whose pass-through payment status will expire on December 31, 2021. This would ensure that we have a full year of claims data from CY 2021 to use for CY 2023 ratesetting and would allow us to avoid using CY 2020 data to set rates for these pass-through drugs, biologicals, and the device category for CY 2022.

We estimated the spending for the drugs, biologicals, and device category for which we proposed to provide separate payment for the remainder of CY 2022 using our equitable adjustment authority. To estimate proposed CY 2022 spending for the one device pass-through category with pass-through status expiring on December 31, 2021, we also used the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778). For this device category, we calculate a proposed spending estimate of $34.5 million. To estimate proposed CY 2022 spending for the six drugs with pass-through status expiring on December 21, 2021 and the 18 drugs and three biologicals with pass-through status expiring on March 30, 2022, June 30, 2022, and September 30, 2022, we performed an analysis similar to the analysis for the first group of drugs and biologicals described earlier in this section where we estimated the pass-through payment amount as the difference between ASP+6 percent and the payment rate for non pass-through drugs and biologicals that will be separately paid. For this group, we calculate a proposed spending estimate for CY 2022 of $44.4 million. We estimate that total spending for these 27 drugs and biologicals and one device category would be approximately $78.9 million for CY 2022. The drugs, biologicals, and device category for which we proposed to provide separate payment for one to four quarters in CY 2022 are listed in Table 43 below. Please refer to section X.F. of this final rule with comment period regarding our decision to implement our proposal to utilize our equitable adjustment authority to pay separately for the remainder of CY 2022 for the device category, drugs, and biologicals with pass-through status that expires between December 31, 2021, and September 30, 2022.

BILLING CODE 4120–01–P

TABLE 43 DEVICE CATEGORY, DRUGS, AND BIOLOGICALS WITH EXPIRING PASS-THROUGH STATUS THAT WOULD RECEIVE SEPARATE PAYMENT FOR ONE TO FOUR QUARTERS IN CY 2022

HCPCS Code	Long Descriptor	Pass-Through Status Effective Date	Pass-Through Status Expiration End Date	Proposed Adjustment Equivalent to an Extension of Pass-through Status (number of quarters)
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads)	01/01/2019	12/31/2021	4
A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	01/01/2019	12/31/2021	4
J0222	Injection, Patisiran, 0.1 mg	01/01/2019	12/31/2021	4
J0291	Injection, plazomicin, 5 mg	01/01/2019	12/31/2021	4
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	01/01/2019	12/31/2021	4
J2798	Injection, risperidone, (perseris), 0.5 mg	01/01/2019	12/31/2021	4
J9204	Injection, mogamulizumab-kpkc, 1 mg	01/01/2019	12/31/2021	4
J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	04/01/2019	03/31/2022	3
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	04/01/2019	03/31/2022	3
J0642	Injection, levoleucovorin 0(khapzory), 0.5 mg	01/01/2020	03/31/2022	3
J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	04/01/2019	03/31/2022	3
J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	04/01/2019	03/31/2022	3
J3245	Injection, tildrakizumab, 1 mg	04/01/2019	03/31/2022	3
J7208	Injection, factor viii, (antihemophilic factor,	04/01/2019	03/31/2022	3

HCPCS Code	Long Descriptor	Pass-Through Status Effective Date	Pass-Through Status Expiration End Date	Proposed Adjustment Equivalent to an Extension of Pass-through Status (number of quarters)
	recombinant), pegylated-aucl (jivi) 1 i.u.			
J9119	Injection, cemiplimab-rwlc, 1 mg	04/01/2019	03/31/2022	3
J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	04/01/2019	03/31/2022	3
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	04/01/2019	03/31/2022	3
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	04/01/2019	03/31/2022	3
Q5111	Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	04/01/2019	03/31/2022	3
C9047	Injection, caplacizumab-yhdp, 1 mg	07/01/2019	06/30/2022	2
J0121	Injection, omadacycline, 1 mg	07/01/2019	06/30/2022	2
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	07/01/2019	06/30/2022	2
J1303	Injection, ravulizumab-cwvz, 10 mg	07/01/2019	06/30/2022	2
J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	07/01/2019	06/30/2022	2
J9210	Injection, emapalumab-lzsg, 1 mg	07/01/2019	06/30/2022	2
J9269	Injection, tagraxofusp-erzs, 10 micrograms	07/01/2019	06/30/2022	2
J3111	Injection, romosozumab-aqqg, 1 mg	10/01/2019	09/30/2022	1
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	10/01/2019	09/30/2022	1

BILLING CODE 4120–01–C

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2022, we proposed to continue with our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of the current clinic and ED hospital outpatient visits policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also proposed to continue our payment policy for critical care services for CY 2022. For a description of the current payment policy for critical care services, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043). In the CY 2022 OPPS/ASC proposed rule, we sought public comments on any changes to these codes that we should consider for future rulemaking cycles. We continue to encourage commenters to provide the data and analysis necessary to justify any suggested changes.

In the CY 2022 OPPS/ASC proposed rule, we stated that we would continue the clinic visit payment policy for CY 2022 and beyond. More specifically, we stated that we would continue to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when

it is furnished by excepted off-campus provider-based departments. The PFS-equivalent rate for CY 2022 is 40 percent of the proposed OPPS payment (that is, 60 percent less than the proposed OPPS rate). Under this policy, these departments will be paid approximately 40 percent of the OPPS rate (100 percent of the OPPS rate minus the 60-percent payment reduction that is applied in CY 2022) for the clinic visit service in CY 2022. We stated that we would continue to monitor the effect of this change in Medicare payment policy, including the volume of these types of OPD services.

Comment: We received several comments on our payment policy for hospital outpatient visits. Many commenters expressed concerns that CMS's policy to pay the PFS-equivalent rate for outpatient clinic visits furnished in excepted off-campus provider-based departments would cause financial harm to hospitals. Other commenters suggested that CMS develop a set of national guidelines for coding ED visits, and a few of commenters provided specific edits to the descriptor of the HCPCS code for hospital outpatient clinic visits (G0463).

Response: We appreciate commenters' concerns and will continue to examine these concerns and determine if any modifications to these policies are warranted in future rulemaking.

After consideration of the public comments, we are finalizing our proposal to continue to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by excepted off-campus provider-based departments as proposed. We are also finalizing our proposal to continue our current ED outpatient visits and critical care payment policies.

VIII. Payment for Partial Hospitalization Services

A. Background

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders. Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional guidance regarding PHP.

In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule (73 FR 68688 through 68697). In CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based (74 FR 60556 through 60559). In CY 2011 (75 FR 71994), we established four separate PHP APC per diem payment rates: Two for CMHCs (APC 0172 and APC 0173) and two for hospital-based PHPs (APC 0175 and APC 0176) and instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data (76 FR 74348 through 74352). In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016, we described our extensive analysis of the claims and cost data and ratesetting methodology, corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers and renumbered the PHP APCs. In CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an eight-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381, and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with

comment period (84 FR 61352). We refer readers to section VIII.D. of the CY 2022 OPPS/ASC proposed rule for a discussion of the proposed updates and the applicability for CY 2021.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized our proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS, excluding outlier payments.

In the April 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID–19 Public Health Emergency (PHE), hospital and CMHC staff are permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, so long as the location meets all conditions of participation to the extent not waived. A hospital or CMHC can furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. These provisions apply only for the duration of the COVID–19 PHE.

In the CY 2021 final rule (85 FR 86073 through 86080), we finalized a CMHC geometric mean per diem cost of $136.14 and a final hospital-based PHP geometric mean per diem cost of $253.76 using the most recent updated claims and cost data. In the CY 2021 proposed rule (85 FR 48901 through 48905), we had proposed, for CY 2021 and subsequent years, to use the CY 2021 CMHC geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for CMHCs of $121.62 that was calculated for CY 2020 ratesetting (84 FR 61339 through 61344), as the basis for developing the CY 2021 CMHC APC per diem rate. We had also proposed, for CY 2021 and subsequent years, to use the CY 2021 hospital-based geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for hospital-based providers of $222.76 that was calculated for CY 2020 ratesetting (84 FR 61344 through 61345). We explained in the CY 2021 final rule that the final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs were significantly higher than each proposed cost floor, therefore a floor was not necessary at the time, and we did not finalize the proposed cost floors in the CY 2021 OPPS/ASC final rule with comment period.

B. PHP APC Update for CY 2022

1. PHP APC Geometric Mean Per Diem Costs

In summary, for CY 2022 only, we proposed to use the CY 2022 CMHC geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for CMHCs of $136.14, which is the final CMHC geometric mean per diem cost calculated last year for CY 2021 ratesetting (85 FR 86080), as the basis for developing the CY 2022 CMHC APC per diem rate. We also proposed, for CY 2022 only, to use the CY 2022 hospital-based geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for hospital-based providers of $253.76 calculated last year for CY 2021 ratesetting (85 FR 86080). Following this methodology, we proposed to use the cost floor value of $136.14 for CMHCs as the basis for developing the CY 2022 CMHC APC per diem rate, and to use the cost floor value of $253.76 as the basis for developing the CY 2021 hospital-based APC per diem rate. We also proposed to use the latest available CY 2019 claims and cost data from the CY 2021 rulemaking to determine CY 2022 geometric mean per diem costs in the CY 2022 OPPS/ASC proposed rule, and we proposed that if the final CY 2022 cost for CMHCs or hospital-based PHPs was calculated to be above the proposed floor for that provider type, we would use the final calculated cost instead of the floor. Lastly, in accordance with our longstanding policy, we proposed to continue to use CMHC APC 5853 (Partial Hospitalization (three or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (three or More Services Per Day)).

We are finalizing these proposals in this CY 2022 OPPS/ASC final rule as proposed, and we discuss our rationale and the public comments received on these proposals in the following sections.

2. Development of the PHP APC Geometric Mean Per Diem Costs

In preparation for CY 2022, we followed the PHP ratesetting methodology described in section VIII.B.2. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466) to calculate the PHP APCs' geometric mean per diem costs and payment rates for APCs 5853 and 5863, incorporating the modifications made in the CY 2017 OPPS/ASC final rule with comment period. As discussed in section VIII.B.1. of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79687), the geometric mean per diem cost for hospital-based PHP APC 5863 is based upon actual hospital-based PHP claims and costs for PHP service days providing three or more services. Similarly, the geometric mean per diem cost for CMHC APC 5853 is based upon actual CMHC claims and costs for CMHC service days providing three or more services. In addition, for CY 2022, we proposed to use cost and charge data from the Hospital Cost Report Information System (HCRIS) as the source for the CMHC cost-to-charge ratios (CCRs), instead of using the Outpatient Provider Specific File (OPSF). As discussed in section VIII.B.2.a of this OPPS/ASC final rule, we are finalizing our proposal to use HCRIS as the source for CMHC CCRs.

As discussed in section X.E of the OPPS/ASC proposed rule (86 FR 42188 through 42190), we analyzed OPPS cost and claims information from CY 2019 and CY 2020 to better understand the effects of the COVID–19 PHE on outpatient services, including PHP, and to identify which data would be the best available for ratesetting. As discussed in that section of the proposed rule, we observed a number of changes, likely as a result of the COVID–19 PHE, in the CY 2020 OPPS claims that we would ordinarily use for ratesetting, and this includes changes in the claims for partial hospitalization, and we continue to observe those changes in the data for this OPPS/ASC final rule. For PHP services in particular, we observe that for hospital-based PHPs, the number of PHP days in our trimmed CY 2020 claims dataset is approximately 49 percent less than the number of PHP days in our trimmed CY 2019 claims dataset; and for CMHCs, the number of PHP days in our trimmed CY 2020 claims dataset is approximately 51 percent less than the number of PHP days in our trimmed CY 2019 claims dataset.

For this CY 2022 ratesetting, we proposed to use CY 2019 claims and the

cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking. We explained that we believe this is appropriate and necessary for PHP services, because of the substantial decrease in the number of PHP days in the CY 2020 claims dataset, which we would normally use for ratesetting. Furthermore, there was a substantial decrease in the number of PHP providers in the CY 2020 data that we continue to observe for this CY 2022 OPPS/ASC final rule. Our trimmed CY 2020 claims dataset for this final rule contains cost and claim information from 31 fewer hospital-based PHP providers than are in the CY 2019 data. These significant decreases in utilization and in the number of hospital-based PHP providers who submitted CY 2020 claims led us to believe that CY 2020 data are not the best overall approximation of expected PHP services in CY 2022. We stated that we believe the CY 2019 data, as the most recent complete calendar year of data prior to the COVID–19 PHE, are a better approximation of expected CY 2022 PHP services. Therefore, as discussed in section X.E of the OPPS/ASC proposed rule (86 FR 42188 through 42190), and consistent with what CMS proposed to do for other APCs under the OPPS, we proposed to use CY 2019 claims and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2022 CMHC and hospital-based PHP APC per diem costs.

Comment: We received 6 comments, which were all in support of our proposal to use the CY 2019 claims and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2022 CMHC and hospital-based PHP APC per diem costs. Several commenters stated their agreement with CMS' assessment that the ongoing COVID–19 PHE has disrupted the provision PHP services, and acknowledged that the proposed PHP payment rate methodology outlined in the proposed rule should help lessen the impact of COVID–19 on providers. One national organization expressed its belief that ensuring financial stability and sustainability for these programs is critical to ensuring access to this level of care for some of Medicare's most vulnerable patients.

Response: We thank commenters for their support. We agree with commenters that ensuring access to PHP services is critical, especially within the context of the COVID–19 PHE. As discussed above, we have analyzed more recent data for this CY 2022 OPPS/ASC final rule, and continue to observe significant changes from the CY 2019 PHP claims, which lead us to continue to believe that the CY 2019 data, as the most recent complete calendar year of data prior to the COVID–19 PHE, are a better approximation of expected CY 2022 PHP services.

After careful consideration of the comments we received and after analyzing more recent data, we are finalizing our proposal to use the CY 2019 claims and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2022 CMHC and hospital-based PHP APC per diem costs.

The CMHC and hospital-based PHP APC per diem costs are the provider-type specific costs derived from the latest updated CY 2019 claims and cost data from the CY 2021 rulemaking. The CMHC and hospital-based PHP APC per diem payment rates are the national unadjusted payment rates calculated from the CMHC and hospital-based PHP APC geometric mean per diem costs, respectively, after applying the OPPS budget neutrality adjustments described in section II.A.4 of this CY 2022 OPPS/ASC final rule.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For this CY 2022 OPPS/ASC final rule, we prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465). However, as discussed above, we finalized our proposal to use CY 2019 claims data and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2022 CMHC PHP APC per diem cost.

For CY 2022 and future years, we also proposed to use cost and charge information from HCRIS as the basis for determining the CMHC CCRs used to calculate the geometric mean per diem cost for CMHC APC 5853. Following the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462), we calculated the CCR based on Medicare costs and charges. However, we noted that CMHCs are now reporting their costs using the newer cost reporting form, Form CMS 2088–17, which has different lines and columns than the ones described in the CY 2016 OPPS/ASC final rule for Form CMS 2088–92. Therefore, to calculate each CMHC's CCR for the CY 2022 OPPS/ASC proposed rulemaking, we divided costs from Worksheet C, Line 50, Column 5 by charges from Worksheet C, Line 50, Column 4.

As noted above, prior to this year's proposed rulemaking, our longstanding methodology for calculating CCRs for CMHCs had been to use the CCRs from the OPSF. As discussed in the CY 2004 OPPS/ASC final rule (68 FR 63468), a Program Memorandum was issued on January 17, 2003, which directed the fiscal intermediaries to recalculate hospital and CMHC cost-to-charge ratios and to update the cost-to-charge ratios on an ongoing basis in the OPSF, which was used as the basis for the CCRs used in calculating the geometric mean per diem costs for CMHCs. Subsequently, in the CY 2009 OPPS/ASC final rule (73 FR 68690), commenters addressed the fact that cost report information for CMHCs was not at that time included in HCRIS, and recommended that CMS base its calculations only in the cost report information that the agency can verify directly and not on data provided by the fiscal intermediary. CMS responded in the same OPPS/ASC final rule that it was working to include CMHC cost reports in the system, but that the CCRs from the OPSF continued to be the best available data for ratesetting. In the CY 2011 OPPS/ASC final rule (75 FR 71993 through 71994), commenters requested that CMHC cost report information be included in HCRIS, and CMS explained that CMHC cost reports would begin to be available in HCRIS starting in early 2011. Since that time, CMHC cost reports have become available in HCRIS. Because the data is now available and consistently populated based on the cost reports that CMHCs submit, we stated that we believe using cost information from HCRIS would be more consistent with the methodology for calculating most other OPPS services, including hospital-based PHP services. Therefore, we proposed for CY 2022 and future years to use HCRIS as the source for CMHC cost information used for calculating the geometric mean per diem cost for CMHC APC 5853.

We did not receive any comments on this proposal, and we are finalizing it as proposed. For CY 2022 and future years, we will use HCRIS as the source for CMHC cost information used for calculating the geometric mean per diem cost for CMHC APC 5853. Accordingly, we used HCRIS as the source for the CMHC cost information for this CY 2022 OPPS/ASC final rule.

Prior to calculating the final geometric mean per diem cost for CMHC APC 5853, we prepared the data by first applying trims and data exclusions, and assessing CCRs as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), so that ratesetting is not skewed by providers with extreme data. Before any trims or exclusions were applied, there were 40 CMHCs in the PHP claims data file. Under the ±2 standard deviation trim policy, we excluded any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day was more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. In applying this trim for CY 2022 ratesetting, one CMHC had geometric mean costs per day below the trim's lower limit of $32.94, and one had geometric mean costs per day above the trim's upper limit of $486.92. Therefore, we are excluding data for ratesetting from these 2 CMHCs.

In accordance with our PHP ratesetting methodology (80 FR 70465), we also remove service days with no wage index values, because we use the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation (80 FR 70465). For this CY 2022 final rule ratesetting, no CMHC was missing wage index data for all of its service days and, therefore, no CMHC was excluded. We also exclude providers without any days containing 3 or more units of PHP-allowable services. One provider is excluded from ratesetting because it had no days containing 3 or more units of PHP-allowable services. In addition to our trims and data exclusions, before calculating the PHP APC geometric mean per diem costs, we also assess CCRs (80 FR 70463). Our longstanding PHP OPPS ratesetting methodology defaults any CMHC CCR that is not available or any CMHC CCR greater than one to the statewide hospital CCR associated with the provider's urban/rural designation and their state location (80 FR 70463). For the CY 2022 OPPS/ASC proposed rule ratesetting and this OPPS/ACS final rule, there are 3 CMHCs with CCRs greater than one, and 12 CMHCs with missing CCR information. Therefore, we are defaulting the CCRs for these 15 CMHCs for ratesetting to the applicable statewide hospital CCR for each CMHC based on its urban/rural designation and its state location.

In summary, the application of these data preparation steps resulted in an adjusted CCR during our ratesetting process for 15 CMHCs having either a CCR greater than one or having no CCR. We are also excluding one CMHC because it had no days containing 3 or more services and 2 CMHCs for failing the ±2 standard deviation trim, resulting in the inclusion of 37 CMHCs. There were 564 CMHC claims removed during data preparation steps due to the ±2 standard deviation trim or because they either had no PHP allowable-codes or had zero payment days, leaving 10,370 CMHC claims in our CY 2022 final rule ratesetting modeling. After applying all of the previously listed trims, exclusions, and adjustments, we followed the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79688, and 79691), using the CMHC CCRs calculated based on the cost information from HCRIS as discussed in this OPPS/ASC final rule, to calculate the CMHC APC geometric mean per diem cost.[185] The calculated CY 2022 geometric mean per diem cost for all CMHCs for providing three or more services per day (CMHC APC 5853) is $129.93, a decrease from $136.14 calculated last year for CY 2021 ratesetting (85 FR 86080).

In the CY 2022 OPPS/ASC proposed rule (86 FR 42151 through 42152), we proposed a cost floor of $136.14, which is equal to the final CY 2021 geometric mean per diem cost for CMHC APC 5853, in order to stabilize the geometric mean per diem costs for CY 2022 only. We recognized the disruption that the ongoing COVID–19 PHE appears to be having on CMHCs' operations, and stated that we believe it is important for CMS to continue to support Medicare beneficiaries' access to critical PHP services during the COVID–19 PHE by helping to maintain the stability of payments to PHP providers. We stated that we were concerned that the calculated geometric mean per diem cost of $130.41 for the proposed rule would result in a disruption to CMHC payments at a time when the need for mental health services has increased.[186]

Because the calculated geometric mean per diem cost for CMHC APC 5853 was below the cost floor, we proposed to calculate the CY 2022 CMHC APC 5853 payment rate based on the cost floor of $136.14. We also proposed that if the final CY 2022 geometric mean per diem cost is calculated to be higher than $136.14, then we would use the calculated geometric mean per diem cost.

Comment: We received 3 comments on our proposed calculation of the geometric mean per diem cost for CMHC APC 5853. All commenters were supportive of the proposed cost floor to stabilize the geometric mean per diem costs finalized in the prior year, CY 2021. Commenters also encouraged CMS to consider long-term approaches to addressing cost fluctuations in PHP services and provide more stable payment rates to ensure access to these important services. Additionally, one commenter urged CMS to consider making CMHCs financially whole, which should include payment that will expand their capacity to meet growing need, particularly in underserved communities.

Response: We appreciate commenters' support for the proposed policies. We agree with commenters about the importance of maintaining stable payment rates to ensure access to PHP services. We continue to recognize that because the CMHC ratesetting dataset is small (n=37), changes in costs from a small number of providers can influence the overall geometric mean per diem cost calculation. We are considering approaches to address cost fluctuations in future years; however, since we did not propose a methodology for future years, we are not finalizing any methodology in this CY 2022 OPPS/ASC final rule to address cost fluctuations in future years.

We also appreciate the commenter's suggestion about the need for ensuring that CMS supports the capacity of CMHCs to meet the growing needs of underserved communities. We recognize the critical role that CMHCs play in the communities they serve. The commenter did not offer specific information about which growing community needs CMHCs are facing or

[185] Each revenue code on the CMHC claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the CMHC's overall CCR (or statewide CCR, where the overall CCR was greater than 1 or was missing) to estimate CMHC costs. Only the claims service lines containing PHP allowable HCPCS codes and PHP allowable revenue codes from the CMHC claims remaining after trimming are retained for CMHC cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. CMHC service days must have three or more services provided to be assigned to CMHC APC 5853. The final geometric mean per diem cost for CMHC APC 5853 is calculated by taking the *n*th root of the product of *n* numbers, for days where three or more services were provided. CMHC service days with costs ±3 standard deviations from the geometric mean costs within APC 5853 are deleted and removed from modeling. The remaining PHP service days are used to calculate the final geometric mean per diem cost for each PHP APC by taking the *n*th root of the product of *n* numbers for days where three or more services were provided.

[186] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e2.htm.*

what mechanism CMS should consider for enabling CMHCs to expand capacity in order to meet these needs, but we note that section 1866(e)(2) of the Act only authorizes Medicare to make payments to CMHCs for PHP services.

We agree with the commenter that PHP payment rates should accurately reflect the financial costs to providers of providing PHP services to their communities. Sections 1833(t)(2) and 1833(t)(9) of the Act set forth the requirements for establishing and adjusting OPPS payment rates, which are based on costs, and which include PHP payment rates. Because our PHP ratesetting methodology depends heavily on provider-reported costs, we strongly encourage CMHCs to review cost reporting instructions to be sure they are reporting their costs correctly. These instructions are available in chapter 45 of the Provider Reimbursement Manual (PRM), Part 2, available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals*. We want to reiterate that it is a requirement for CMHCs, unless they are approved as a low-utilization or no-utilization provider in accordance with PRM–1, chapter 1, section 110 (42 CFR 413.24(g) and (h)), to file full cost reports, which helps us capture accurate CMHC costs in rate setting. We furthermore encourage those CMHCs that do not file full cost reports to consider doing so.

After careful consideration of the comments received, we are finalizing our proposal to establish a cost floor for CY 2022 equal to the final CY 2021 geometric mean per diem cost for CMHC APC 5853, which is $136.14. The calculated CY 2022 geometric mean per diem cost for all CMHCs for providing three or more services per day (CMHC APC 5853) is $129.93. Because this amount is below the cost floor, we are finalizing our proposal to calculate the CY 2022 CMHC APC 5853 payment rate based on the cost floor of $136.14.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For this CY 2022 final rule, we prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for hospital-based PHP providers, which is similar to that used for CMHCs. However, as discussed above, we finalized our proposal to use CY 2019 claims data and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2022 hospital-based PHP APC per diem cost. The CY 2019 PHP claims included data for 449 hospital-based PHP providers for our calculations in the CY 2022 OPPS/ASC final rule.

Consistent with our policies, as stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), we prepared the data by applying trims and data exclusions. We applied a trim on hospital service days for hospital-based PHP providers with a CCR greater than 5 at the cost center level. To be clear, the CCR greater than 5 trim is a service day-level trim in contrast to the CMHC ±2 standard deviation trim, which is a provider-level trim. Applying the CCR greater than 5 trim removed affected service days from one hospital-based PHP provider from our proposed ratesetting. However, 100 percent of the service days for this hospital-based PHP provider had at least one service associated with a CCR greater than 5, so the trim removed this provider entirely from our proposed ratesetting. In addition, 68 hospital-based PHPs were removed for having no days with PHP payment. Two hospital-based PHPs were removed because none of their days included PHP-allowable HCPCS codes. No hospital-based PHPs were removed for missing wage index data, and a single hospital-based PHP was removed by the OPPS ±3 standard deviation trim on costs per day. (We refer readers to the OPPS Claims Accounting Document, available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*).[187]

Overall, we removed 72 hospital-based PHP providers (1 with all service days having a CCR greater than 5) + (68 with no PHP payment) + (2 with no PHP-allowable HCPCS codes) + (1 provider with geometric mean costs per day outside the ± 3 SD limits)], resulting in 377 (449 total − 72 excluded) hospital-based PHP providers in the data used for calculating ratesetting.

After completing these data preparation steps, we calculated the CY 2022 geometric mean per diem cost for hospital-based PHP APC 5863 by following the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 and 79691).[188] The calculated CY 2022 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide three or more services per service day (hospital-based PHP APC 5863) is $253.02, which is a very slight decrease from $253.76 calculated last year for CY 2021 ratesetting (85 FR 86080).

In the CY 2022 OPPS/ASC proposed rule (86 FR 42151 through 42152), we proposed a cost floor of $253.76, which is equal to the final CY 2021 geometric mean per diem cost for CMHC APC 5863, in order to stabilize the geometric mean per diem costs for CY 2022 only. We noted that, in general, a decrease of the magnitude calculated for the proposed rule would not be unexpected due to normal variation in cost and claims data. However, we recognized the disruption that the ongoing COVID–19 PHE appears to be having on the operations of hospital-based PHPs, and stated that we believe it is important for CMS to continue to support Medicare beneficiaries' access to critical PHP services during the COVID–19 PHE by helping to maintain the stability of payments to PHP providers. We stated that while the decrease in the geometric mean per diem cost for hospital-based PHP APC 5863 would be very slight based on the CY 2019 claims and cost data used for the CY 2022 OPPS/ASC proposed rule, we continue to believe, as we have stated before in recent years, that access is better supported when geometric mean per diem costs do not fluctuate greatly. We also noted that the proposed cost floor would protect access to PHP services at hospital-based PHPs if the final CY 2022 calculated hospital-based PHP APC geometric mean per diem cost is significantly less,

[187] Click on the link labeled ''CY 2022 OPPS/ASC Notice of Proposed Rulemaking'', which can be found under the heading ''Hospital Outpatient Prospective Payment System Rulemaking'' and open the claims accounting document link at the bottom of the page, which is labeled ''2022 NPRM OPPS Claims Accounting (PDF)''.

[188] Each revenue code on the hospital-based PHP claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the hospital's department-level CCR; in CY 2020 and subsequent years, that CCR is determined by using the PHP-only revenue-code-to-cost-center crosswalk. Only the claims service lines containing PHP-allowable HCPCS codes and PHP-allowable revenue codes from the hospital-based PHP claims remaining after trimming are retained for hospital-based PHP cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. Hospital-based PHP service days must have three or more services provided to be assigned to hospital-based PHP APC 5863. The final geometric mean per diem cost for hospital-based PHP APC 5863 is calculated by taking the *n*th root of the product of *n* numbers, for days where three or more services were provided. Hospital-based PHP service days with costs ±3 standard deviations from the geometric mean costs within APC 5863 are deleted and removed from modeling. The remaining hospital-based PHP service days are used to calculate the final geometric mean per diem cost for hospital-based PHP APC 5863.

which we were concerned would result in a disruption to hospital-based PHP payments at a time when the need for mental health services has increased.

Because the calculated geometric mean per diem cost for hospital-based PHP APC 5863 was below the cost floor, we proposed to calculate the CY 2022 hospital-based PHP APC 5863 payment rate based on the cost floor of $253.76. We also proposed that if the final CY 2022 geometric mean per diem cost is calculated to be higher than $253.76, then we would use the calculated geometric mean per diem cost.

Comment: We received 5 comments on our proposed calculation of the geometric mean per diem cost for CMHC APC 5863. All commenters were supportive of the proposed cost floor to stabilize the geometric mean per diem costs finalized in the prior year, CY 2021. Commenters also encouraged CMS to consider long-term approaches to addressing cost fluctuations in PHP services and provide more stable payment rates to ensure access to these important services. Three national provider associations commented that while the PHE has magnified the need for improved access to behavioral healthcare, there are severe shortages of behavioral healthcare providers in many parts of the United States, stating their belief that the proposed ratesetting methodology should help lessen the impact of COVID–19 on PHP providers.

Response: We appreciate commenters' support for the proposed policies. We share commenters' concerns about ensuring that Medicare beneficiaries continue to have access to PHP services, particularly in light of the impact of the COVID–19 PHE. We also continue to recognize, as we have noted in past years, that changes in costs from a small number of providers can influence the overall geometric mean per diem cost calculation. We are considering approaches to address cost fluctuations in future years; however, since we did not propose a methodology for future years, we are not finalizing any methodology in this CY 2022 OPPS/ASC final rule to address cost fluctuations in future years.

After careful consideration of the comments received, we are finalizing our proposal to establish a cost floor for CY 2022 equal to the final CY 2021 geometric mean per diem cost for CMHC APC 5863, which is $253.76. The calculated CY 2022 geometric mean per diem cost for all hospital-based PHPs for providing three or more services per day (CMHC APC 5863) is $253.02. Because this amount is below the cost floor, we are finalizing our proposal to calculate the CY 2022 hospital-based PHP APC 5863 payment rate based on the cost floor of $253.76.The final CY 2022 PHP geometric mean per diem costs are shown in Table 44 and are used to derive the proposed CY 2022 PHP APC per diem rates for CMHCs and hospital-based PHPs. The final CY 2022 PHP APC per diem rates are included in Addendum A to the CY 2022 OPPS/ASC proposed rule (which is available on our website at:*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*).[189]

TABLE 44: CY 2022 PHP APC Geometric Mean Per Diem Costs

CY 2022 APC	Group Title	Final PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (three or more services per day) for CMHCs	$136.14
5863	Partial Hospitalization (three or more services per day) for hospital-based PHPs	$253.76

C. Outlier Policy for CMHCs

For 2022, we proposed to continue to calculate the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed dollar-threshold according to previously established policies. These topics are discussed in more detail. We refer readers to section II.G.1 of this CY 2022 OPPS/ASC final rule for our general policies for hospital outpatient outlier payments.

We did not receive any public comments on our proposal, and are finalizing it as proposed.

1. Background

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we noted a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. Given the difference in PHP charges between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Therefore, beginning in CY 2004, we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs. This

[189] As discussed in section XX. of the CY 2022 OPPS/ASC proposed rule, OPPS APC geometric mean per diem costs (including PHP APC geometric mean per diem costs) are divided by the geometric mean per diem costs for APC 5012 (Clinic Visits and Related Services) to calculate each PHP APC's unscaled relative payment weight. An unscaled relative payment weight is one that is not yet adjusted for budget neutrality. Budget neutrality is required under section 1833(t)(9)(B) of the Act, and ensures that the estimated aggregate weight under the OPPS for a calendar year is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To adjust for budget neutrality (that is, to scale the weights), we compare the estimated aggregated weight using the scaled relative payment weights from the previous calendar year at issue. We refer readers to the ratesetting procedures described in Part 2 of the OPPS Claims Accounting narrative and in section II. of the CY 2022 OPPS/ASC proposed rule for more information on scaling the weights, and for details on the final steps of the process that leads to final PHP APC per diem payment rates. The OPPS Claims Accounting narrative is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004 and $0.5 million in outlier payments to CMHCs in CY 2005 (82 FR 59381). In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments (82 FR 59381).

2. CMHC Outlier Percentage

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII.C. of that same final rule (82 FR 59381). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082).

We estimate CMHC per diem payments and outlier payments by using the most recent available utilization and charges from CMHC claims, updated CCRs, and the updated payment rate for APC 5853. For increased transparency, we are providing a more detailed explanation of the existing calculation process for determining the CMHC outlier percentages. To calculate the CMHC outlier percentage, we follow three steps:

- Step 1: We multiply the OPPS outlier threshold, which is 1.0 percent, by the total estimated OPPS Medicare payments (before outliers) for the prospective year to calculate the estimated total OPPS outlier payments: (0.01 × Estimated Total OPPS Payments) = Estimated Total OPPS Outlier Payments.
- Step 2: We estimate CMHC outlier payments by taking each provider's estimated costs (based on their allowable charges multiplied by the provider's CCR) minus each provider's estimated CMHC outlier multiplier threshold (we refer readers to section VIII.C.3. of the CY 2022 OPPS/ASC proposed rule). That threshold is determined by multiplying the provider's estimated paid days by 3.4 times the CMHC PHP APC payment rate. If the provider's costs exceed the threshold, we multiply that excess by 50 percent, as described in section VIII.C.3. of the CY 2022 OPPS/ASC proposed rule, to determine the estimated outlier payments for that provider. CMHC outlier payments are capped at 8 percent of the provider's estimated total per diem payments (including the beneficiary's copayment), as described in section VIII.C.5. of the CY 2022 OPPS/ASC proposed rule, so any provider's costs that exceed the CMHC outlier cap will have its payments adjusted downward. After accounting for the CMHC outlier cap, we sum all of the estimated outlier payments to determine the estimated total CMHC outlier payments. (Each Provider's Estimated Costs − Each Provider's Estimated Multiplier Threshold) = A. If A is greater than 0, then (A × 0.50) = Estimated CMHC Outlier Payment (before cap) = B. If B is greater than (0.08 × Provider's Total Estimated Per Diem Payments), then cap adjusted B = (0.08 × Provider's Total Estimated Per Diem Payments); otherwise, B = B. Sum (B or cap-adjusted B) for Each Provider = Total CMHC Outlier Payments.
- Step 3: We determine the percentage of all OPPS outlier payments that CMHCs represent by dividing the estimated CMHC outlier payments from Step 2 by the total OPPS outlier payments from Step 1: (Estimated CMHC Outlier Payments/Total OPPS Outlier Payments).

We proposed to continue to calculate the CMHC outlier percentage according to previously established policies, and we did not propose any changes to our current methodology for calculating the CMHC outlier percentage for CY 2022. Therefore, based on our CY 2022 payment estimates, CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2022, excluding outlier payments. We proposed to designate approximately less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold for CMHCs. This percentage is based upon the formula given in Step 3.

We did not receive any public comments on our proposal, and are finalizing it as proposed.

3. Cutoff Point and Percentage Payment Amount

As described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). For CY 2018, the highest CMHC PHP APC payment rate is the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP APC geometric mean per diem costs over the cutoff point. For example, for CY 2018, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853 [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))]. This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 through 58997), CY 2020 OPPS/ASC final rule with comment period (84 FR 61351) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082 through 86083). For CY 2022, we proposed to continue to pay for partial hospitalization services that exceed 3.4 times the proposed CMHC PHP APC payment rate at 50 percent of the CMHC PHP APC geometric mean per diem costs over the cutoff point. That is, for CY 2022, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the payment rate for CMHC APC 5853, the outlier payment will be calculated as [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))].

We did not receive any public comments on our proposal, and are finalizing it as proposed.

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that lead to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and would apply to all hospitals and CMHCs paid under the OPPS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and

complex service, but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 through 58875 and 81 FR 79678 through 79680).

We proposed to continue these policies for partial hospitalization services provided through PHPs for CY 2022. The current outlier reconciliation policy requires that providers whose outlier payments meet a specified threshold (currently $500,000 for hospitals and any outlier payments for CMHCs) and whose overall ancillary CCRs change by plus or minus 10 percentage points or more, are subject to outlier reconciliation, pending approval of the CMS Central Office and Regional Office (73 FR 68596 through 68599). The policy also includes provisions related to CCRs and to calculating the time value of money for reconciled outlier payments due to or due from Medicare, as detailed in the CY 2009 OPPS/ASC final rule with comment period and in the Medicare Claims Processing Manual (73 FR 68595 through 68599 and Medicare Claims Processing Internet Only Manual, Chapter 4, Section 10.7.2 and its subsections, available online at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf*).

We did not receive any public comments on our proposal, and are finalizing it as proposed.

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). We finalized the CMHC outlier payment cap to be set at 8 percent of the CMHC's total per diem payments (81 FR 79694 through 79695). This outlier payment cap only affects CMHCs, it does not affect other provider types (that is, hospital-based PHPs), and is in addition to and separate from the current outlier policy and reconciliation policy in effect. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), we finalized a proposal to continue this policy in CY 2020 and subsequent years. In the CY 2022 OPPS/ASC proposed rule, we did not propose any changes to this policy.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. CMHC PHP APC 5853 is the only APC for which CMHCs may receive payment under the OPPS, and is for providing a defined set of services that are relatively low cost when compared to other OPPS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APC 5853, it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381). This same policy was also reiterated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083). We proposed to continue this policy for CY 2022.

We did not receive any public comments on our proposal, and are finalizing it as proposed.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

Established in rulemaking as part of the initial implementation of the OPPS, the inpatient only (IPO) list identifies services for which Medicare will only make payment when the services are furnished in the inpatient hospital setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged (70 FR 68695). The IPO list was created based on the premise (rooted in the practice of medicine at that time), that Medicare should not pay for procedures furnished as outpatient services that are performed on an inpatient basis virtually all of the time for the Medicare population, either because of the invasive nature of the procedures, the need for postoperative care, or the underlying physical condition of the patient who would require such surgery, because performing these procedures on an outpatient basis would not be safe or appropriate, and therefore not reasonable and necessary under Medicare rules (63 FR 47571). Services included on the IPO list were those determined to require inpatient care, such as those that are highly invasive, result in major blood loss or temporary deficits of organ systems (such as neurological impairment or respiratory insufficiency), or otherwise require intensive or extensive postoperative care (65 FR 67826). There are some services designated as inpatient only that, given their clinical intensity, would not be expected to be performed in the hospital outpatient setting. For example, we have traditionally considered certain surgically invasive procedures on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies, to require inpatient care (65 FR 18456). Designation of a service as inpatient-only does not preclude the service from being furnished in a hospital outpatient setting, but means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting (65 FR 18443). Conversely, the absence of a procedure from the list should not be interpreted as identifying those procedures as appropriately performed only in the hospital outpatient setting (70 FR 68696).

As part of the annual update process, we have historically worked with interested stakeholders, including professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and to determine whether services should be added to or removed from the list. Stakeholders were encouraged to request reviews for a particular code or group of codes; and we have asked that their requests include evidence that demonstrates that the procedure was performed on an outpatient basis in a safe and appropriate manner in a variety of different types of hospitals—including but not limited to—operative reports of actual cases, peer-reviewed medical literature, community medical standards and practice, physician comments, outcome data, and post-procedure care data (67 FR 66740).

Prior to CY 2021, we traditionally used five criteria to determine whether a procedure should be removed from the IPO list (65 FR 18455). As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we assessed whether a procedure or service met these criteria to determine whether or not it should be removed from the IPO list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. We have explained that a

procedure is not required to meet all of the established criteria to be removed from the IPO list. The criteria for assessing procedures for removal from the IPO list prior to CY 2021 are the following:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be furnished in most outpatient departments.
- The procedure is related to codes that we have already removed from the IPO list.
- A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC list.

In the past, we have requested that stakeholders submit corresponding evidence in support of their claims that a code or group of codes met the longstanding criteria for removal from the IPO list and was safe to perform on the Medicare population in the hospital outpatient setting—including, but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols. Our clinicians thoroughly reviewed all information submitted within the context of the established criteria and if, following this review, we determined that there was sufficient evidence to confirm that the code could be safely and appropriately performed on an outpatient basis, we assigned the service to an APC and included it as a payable procedure under OPPS (67 FR 66740).

We stated in prior rulemaking that, over time, given advances in technology and surgical technique, we would continue to evaluate services to determine whether they should be removed from the IPO list. Our goal is to ensure that inpatient only designations are consistent with current standards of practice. We have asserted in prior rulemaking that, insofar as advances in medical practice mitigate concerns about these procedures being performed on an outpatient basis, we would be prepared to remove procedures from the IPO list and provide for payment for them under the OPPS (65 FR 18443). Prior to CY 2021, changes to the IPO list have been gradual. Further, CMS has at times had to reclassify codes as inpatient only services with the emergence of new information.

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full discussion of our historic policies for identifying services that are typically provided only in an inpatient setting and, therefore, that will not be paid by Medicare under the OPPS, as well as the criteria we have used to review the IPO list to determine whether or not any services should be removed.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86084 through 86088), we significantly adjusted our approach to the IPO list. As we stated in that final rule, we no longer saw the need for CMS to restrict payment for certain procedures by maintaining the IPO list to identify services that require inpatient care. In that final rule, we acknowledged the seriousness of the concerns regarding patient safety and quality of care that various stakeholders expressed regarding removing procedures from the IPO list or eliminating the IPO list altogether. But we stated that we believed that the developments in surgical technique and technological advances in the practice of medicine, as well as various safeguards, including, but not limited to, physician clinical judgment, state and local regulations, accreditation requirements, medical malpractice laws, hospital conditions of participation, CMS quality and monitoring initiatives and programs and other CMS initiatives would continue to ensure that procedures removed from the IPO list and provided in the hospital outpatient setting could be performed safely on appropriately selected beneficiaries. We also stated that given our increasing ability to measure the safety of procedures performed in the hospital outpatient setting and to monitor the quality of care, in addition to the other safeguards detailed above, we believed that quality of care was unlikely to be affected by the elimination of the IPO list. We noted that we do not require services that are not included on the IPO list to be performed solely in the hospital outpatient setting and that services that were previously identified as inpatient only can continue to be performed in the inpatient setting. We emphasized that physicians should use their clinical knowledge and judgment, together with consideration of the beneficiary's specific needs, to determine whether a procedure can be performed appropriately in a hospital outpatient setting or whether inpatient care is required for the beneficiary, subject to the general coverage rules requiring that any procedure be reasonable and necessary. We also stated that the elimination of the IPO list would ensure maximum availability of services to beneficiaries in the hospital outpatient setting. Finally, we stressed that as medical practice continues to develop, we believed that the difference between the need for inpatient care and the appropriateness of outpatient care has become less distinct for many services.

Accordingly, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86084 through 86088), we finalized, with modification, our proposal to eliminate the IPO list over the course of three years (85 FR 86093). We revised our regulation at § 419.22(n) to state that, effective on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition. As part of the first phase of this elimination of the IPO list, we removed 298 codes, including 266 musculoskeletal-related services, from the list beginning in CY 2021 and, because we proposed to eliminate the IPO list entirely, the removed procedures were not assessed against our longstanding criteria for removal (85 FR 86094).

B. Changes to the Inpatient Only (IPO) List

In the CY 2022 OPPS/ASC proposed rule, for CY 2022, we proposed to halt the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021 as part of the first phase of eliminating the IPO list, we proposed to add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022. In accordance with this proposal, we proposed to amend the regulation at § 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a three-year transition. We also proposed to codify the five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation in a new § 419.23.

1. Proposal To Halt the Elimination of the IPO List

Following the CY 2021 OPPS/ASC final rule with comment period, stakeholders continued to express concerns regarding the pace at which the IPO list would be eliminated, the perceived lack of transparency in determining the order of removal of procedures over the course of the elimination process, and what stakeholders believed were insufficient

details concerning rate setting for procedures for which payment would be made when furnished in the hospital outpatient department (HOPD) setting, as well as the accuracy of those rates for the HOPD setting. We have received stakeholder requests to reconsider the elimination of the IPO list, to reevaluate procedures removed from the IPO list due to safety and quality concerns, and to, at a minimum, extend the timeframe for eliminating the list.

In the CY 2022 OPPS/ASC proposed rule, we stated that after further consideration of the policy we adopted in the CY 2021 OPPS/ASC final rule with comment period and the concerns stakeholders have raised since the final rule was issued, we believe that we should halt the elimination of the IPO list to ensure that any service removed from the IPO list is evaluated against the previous longstanding criteria for removal from the IPO list before it is removed. We stated that we believe assessing whether a procedure or service meets the criteria for removal would allow for a more gradual removal of services from the IPO list—which would also allow stakeholders more time to evaluate the safety of the service in the HOPD and to prepare to safely furnish the services migrating off of the IPO list, if they so choose. We stated that after further consideration, we continue to believe that the IPO list is a valuable tool for ensuring that the OPPS only pays for services that can safely be performed in the hospital outpatient setting, and we had therefore reconsidered eliminating the IPO list at that time. We stated that we believe that there are many surgical procedures that cannot be safely performed on a typical Medicare beneficiary in the hospital outpatient setting, and therefore, it would be inappropriate for us to assign them separately payable status indicators and establish payment rates in the OPPS (78 FR 75055). We recognized that while physicians are able to make safety determinations for a specific beneficiary, CMS is in the position to make safety determinations for the broader population of Medicare beneficiaries, that is, the typical Medicare beneficiary. Furthermore, we explained that while we want to afford physicians and hospitals the maximum flexibility in choosing the most clinically appropriate site of service for the procedure, as long as the characteristics of the procedure are consistent with the criteria listed above, we believe that the IPO list was a necessary safeguard that considers the broader Medicare population.

In the CY 2021 OPPS/ASC final rule with comment period, we recognized that stakeholders may need time to adjust to the removal of procedures from the list, especially given the significant number of services removed beginning in CY 2021 (85 FR 86085 and 86092). We also recognized that providers may need time to prepare, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the IPPS or the OPPS (85 FR 86086). We also acknowledged that it will take time for clinical staff and providers to gain experience furnishing these services to the appropriate Medicare beneficiaries in the HOPD, and to develop comprehensive patient selection criteria and other protocols to identify whether a beneficiary can safely have these procedures performed in the hospital outpatient setting (85 FR 86088). In the CY 2021 OPPS/ASC proposed rule, we also reiterated that the removal of a particular procedure from the IPO list does not require that all beneficiaries be treated in the hospital outpatient setting, but explained that we are cognizant that it does require the physician and clinical care team to exercise complex medical judgment to determine the appropriate setting of care, in accordance with the 2-midnight rule.

Separately, we also acknowledged the numerous challenges that providers are facing due to the COVID–19 PHE (85 FR 86089). After further experience with the PHE and its impact on provider and beneficiary behavior, we recognized that the COVID–19 PHE has likely reduced providers' ability to prepare to furnish these services in the hospital outpatient setting in the manner they would absent the PHE. We acknowledged that the COVID–19 PHE may have negatively impacted the time and resources that providers have to adapt to the removal of these procedures from the IPO list—making it more difficult for providers to prepare, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the IPPS or the OPPS. We also recognized that the COVID–19 PHE has negatively impacted clinical staff and providers' opportunity to develop the comprehensive patient selection criteria and other protocols necessary to identify whether a Medicare beneficiary could safely have these procedures performed in the hospital outpatient setting while guaranteeing them appropriate quality of care.

We explained in the CY 2022 OPPS/ASC proposed rule that after further consideration and review of the additional feedback from stakeholders, we recognized that the timeframe we finalized in the CY 2021 OPPS/ASC final rule with comment period for eliminating the IPO list did not, and would not, give us a sufficient opportunity to carefully assess whether a procedure should be payable in the HOPD setting, with considerations to beneficiary safety and medical advancements. We also explained that the unprecedented removal of the 298 codes from the IPO list transpired quickly. Given the significant policy shift and work required to operationalize the elimination of the IPO list, we acknowledged that more time is required to separately evaluate and consider the inpatient only classification of each service and its potential APC assignment. In addition, we stated that we believe that we should continue to use the longstanding criteria for removing services from the IPO list to evaluate each service before proposing to remove it from the list, and, as noted above, we proposed to codify these criteria in the regulation in a new § 419.23.

We emphasized in the CY 2022 OPPS/ASC proposed rule that we still believe that as medical practice continues to develop, the difference between the need for inpatient care and the appropriateness of outpatient care has become less distinct for many services. We stated that while we recognize that there are services currently classified as inpatient only that may be appropriate in the hospital outpatient setting for some Medicare beneficiaries, we continue to strive to balance the goals of increasing physician and patient choice of setting of care with considerations to patient safety for all Medicare beneficiaries. We explained that we must also consider the timing with which we remove services from the IPO list and the availability of evidence that may support the removal of those services. We stated that we believe that with additional time stakeholders can provide supportive evidence to aid in the evaluation of each individual procedure's assignment to the IPO list, as well as the appropriate APC assignment and corresponding payment for any codes, including but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols.

Furthermore, we explained that an initial review of 2021 billing data through May 21, 2021 supported our proposal to halt the elimination of the list, revealing that 131 of the 298 codes removed from the IPO list in the CY 2021 OPPS/ASC final rule with comment period appeared on either zero or one OPPS claim and 269 of the 298

codes appeared on fewer than 100 claims. These data indicated that fewer than 3 percent of the services removed from the IPO list in 2021 had seen notable volume in the hospital outpatient setting following their removal from the IPO list. For perspective, we also note that even before we removed these codes from the IPO list, it was not uncommon to see at least some volume for these codes in the claims data. In CY 2020, when these codes were still not payable under the OPPS, 188 of the codes had at least one outpatient claim and 18 codes had greater than 100 claims, for reasons undetermined. We stated that, as a result, it was likely that not all of the reported claims represent services provided in the hospital outpatient setting due to these services being removed from the IPO list in CY 2021.

Therefore, we proposed to halt the elimination of the IPO list in order to allow for greater consideration of the impact removing services from the list has on beneficiary safety and to allow providers impacted by the COVID–19 PHE additional time to prepare to furnish appropriate services safely and efficiently before continuing to remove large numbers of services from the list.

Comment: Many commenters, including hospital associations, health systems, medical specialty societies, professional organizations, and advocacy groups supported our proposal to halt the elimination of the IPO list. Several commenters thanked CMS for listening to stakeholders' concerns about beneficiary safety and reconsidering the elimination of the IPO list. Commenters stated that the IPO list is a necessary tool and an important programmatic safeguard, and that maintaining the IPO list is necessary to set a national standard for services that should be restricted to the inpatient setting.

Specifically, commenters who supported halting the elimination of the IPO list wanted to maintain the IPO list due to patient safety concerns. These commenters stated that the high-risk, invasive procedures that require post-operative monitoring and care coordination that are included on the IPO list would not be safe to perform on Medicare beneficiaries in the hospital outpatient setting. Commenters noted that complications can occur with any surgical procedure, particularly during the post-operative period and that for many services on the IPO list, such post-operative complications are best identified early and treated promptly in the inpatient hospital setting. Several commenters responded that even with future advancements in medical practice and technology, they could not anticipate that such complicated procedures could ever be provided safely in the hospital outpatient setting, given their clinical nature. Commenters noted that physicians are in the best position to make safety determinations for their patients, but CMS must make policies for the broader, average beneficiary population. The commenters suggested that a careful review is needed before removing extensive surgical procedures performed on patients with complications and/or comorbidities, which are common in the Medicare population.

Supporters of maintaining the IPO list acknowledged operational and administrative concerns with maintaining the IPO list, largely focused on the 2-midnight rule and burden of proof required to allow services removed from the IPO list to be furnished inpatient, but contended that eliminating the IPO list would create new clinical and operational challenges for both practitioners and facilities that would require additional time and resources to adjust to. Several commenters also expressed concerns that the elimination of the IPO list could potentially inappropriately shift costs onto patients and subsequently discourage beneficiaries from seeking necessary care. Most supporters of maintaining the IPO list also supported CMS retaining its current process for evaluating and removing procedures from the IPO list through rulemaking.

Response: We thank the commenters for their support and we refer readers to sections 1X.B.2. and B.4. of this final rule with comment period for additional discussion of commenters' feedback on policy modifications, including whether CMS should maintain the longer-term objective of eliminating the IPO list or maintain the IPO list but continue to systematically scale the list back so that inpatient only designations are consistent with current standards of practice.

Comment: We also received comments from physicians and medical specialty societies who stated that, while they agreed that physicians should be the primary arbiters regarding the clinically appropriate site of service for a procedure for a particular beneficiary, they support maintaining the IPO list because a physician's medical judgment is not always the primary factor in determining whether a procedure is furnished in the inpatient or outpatient hospital setting. These commenters stated that many of the adverse impacts from removing procedures from the IPO list arise from hospitals that drive provider admission decisions. These commenters noted that when procedures are removed from the IPO list, many hospitals and other payers, including Medicare Advantage plans, make rules establishing outpatient status as the assumed baseline site of service for these procedures, regardless of patient characteristics or the physician's clinical assessment. Commenters divulged various reasons for this action on the part of hospitals and payers, including a desire to have the procedure performed in a lower cost setting, misinterpretation of CMS' rulemaking guidance, a desire for administrative simplicity, concerns regarding the application of the 2-midnight benchmark to services that are removed from the IPO list, the potential for claim denials if this benchmark is not met and/or excessive administrative burden to support the case-by-case exception to the 2-midnight rule. According to commenters, physicians must, at times, convince a hospital or payer that a particular patient should receive a given procedure in an inpatient setting due to patient safety concerns.

Commenters requested that CMS provide robust stakeholder education and issue various forms of guidance as a means of reducing administrative and operational burden, to support site of service decisions and to encourage consideration of and deference to the judgment of the physician, professional societies, and hospital associations regarding the procedures that are appropriate to be performed in the HOPD setting. Commenters referenced prior CMS guidance as a useful tool for providers and hospitals. One commenter noted that guidance increases the likelihood of hospital awareness of CMS preamble statements on patient selection. One commenter acknowledged CMS' historical reticence to define clinical criteria in light of our deference to physician judgment but reasoned that a CMS-established baseline protocol would not limit clinical decision-making, as clinicians would still be able to provide supporting clinical documentation to justify inpatient stays for patients that may otherwise be candidates for outpatient surgery. Commenters also requested that CMS institute a safeguard against inappropriate payer behavior that requires services to be furnished in the HOPD setting, despite the clinical judgment of the physician or needs of the patient.

Response: We thank the commenters for their support and we acknowledge the commenters' concerns regarding the administrative burden associated with the IPO list and the removal of

procedures from the list. As we have stated in previous rulemaking (85 FR 86087; 84 FR 61354; 82 FR 59384; 81 FR 79697) when commenters raised similar concerns, the removal of a service from the IPO list does not require the service to be performed only on an outpatient basis. Rather, it allows for payment under the OPPS when the service is performed on a registered hospital outpatient. We reiterate that services that are removed from the IPO list can be and are performed on individuals who are admitted as inpatients (as well as individuals who are registered hospital outpatients) when the patient's condition warrants inpatient admission (65 FR 18456). It is a misinterpretation of CMS payment policy for providers to create policies or guidelines that establish the hospital outpatient setting as the baseline or default site of service for a procedure based on its removal from the IPO list. As stated in previous rulemaking, services that are no longer included on the IPO list are payable in either the inpatient or hospital outpatient setting subject to the general coverage rules requiring that any procedure be reasonable and necessary, and payment should be made pursuant to the otherwise applicable payment policies (84 FR 61354; 82 FR 59384; 81 FR 79697).

We also recognize commenters' concerns regarding the need for additional stakeholder education on considerations that would support physician decision-making in selecting an appropriate site of service for procedures furnished to Medicare beneficiaries. We note the balance between several factors on this important issue, namely, the prohibition on CMS interfering with the practice of medicine in Section 1801 of the Social Security Act, the need to provide clear information about CMS billing and payment rules that ensures hospitals, physicians and other stakeholders can understand and operate within them, and that the specific decision about the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary (84 FR 61354). We note that, in the past when services have come off the IPO list, we have attempted to provide general educational information regarding our billing and payment rules. For example, we published Medicare Learning Network (MLN) Booklet 909065 regarding major hip and knee replacement procedures, which is available here: *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/jointreplacement-ICN909065.pdf*.

We also note the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs) are contracted by CMS to review a sample of Medicare fee-for-service (FFS) short-stay inpatient claims (claims with hospital stays lasting less than 2 midnights after formal inpatient admission) for compliance with the 2-Midnight Rule. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61364 through 61365) the BFCC–QIO program adopted a period of exemption from certain medical review activities for procedures newly removed from the IPO list where the length of stay after inpatient admission is less than 2 midnights. During the exemption period, BFCC–QIOs may conduct medical reviews for education purposes but will not deny claims or make referrals to RACs for noncompliance with the 2-midnight rule for procedures that are removed from the IPO list within the first 2 years of their removal. This exemption period was intended to allow providers time to become more familiar with the application of the 2-midnight rule to procedures newly removed from the IPO list, and allows the BFCC–QIOs the opportunity to provide education regarding application of that payment policy to such procedures. In section X.A of this CY 2022 OPPS/ASC final rule with comment period we are reinstating this 2-year exemption policy, and believe that this will give providers needed time to adapt when procedures are newly removed from the IPO list starting January 1, 2022.

In addition to the 2-year exemption period for certain medical review activities, in the coming months we plan to use our experience gained through BFCC–QIO reviews to engage stakeholders to determine if developing additional materials for services that are newly removed from the IPO list would be helpful, including materials that are similar to MLN Booklet 909065 noted above. We reiterate that any such materials will not supersede physicians' medical judgment about whether a procedure should be performed in the inpatient or outpatient hospital setting. With regard to the behavior of commercial payers and site selection for outpatient services, we believe that these comments are out of the scope of the proposed rule.

We refer readers to section X. of this final rule with comment period for additional discussion regarding the 2-midnight rule. We also refer readers to sections 1X.B.2. and B.4. of this final rule with comment period for additional discussion of commenters' feedback on policy modifications, including whether CMS should maintain the longer-term objective of eliminating the IPO list or maintain the IPO list but continue to systematically scale the list back so that inpatient only designations are consistent with current standards of practice.

Comment: Numerous commenters, including some health systems, individual physicians and certain payers, opposed halting the elimination of the IPO list. Most of these commenters opposed halting the elimination of the IPO list due to administrative and operational issues that they believe stem from the existence of the IPO list, including site of service claims denials and compliance documentation. Other commenters contended that eliminating the IPO list would reduce administrative and operational burden and allow for necessary flexibility that could help providers serve the diversity of clinical needs and health statuses among Medicare beneficiaries and would increase patient choice and access to advances in surgical care that have made outpatient procedures safe, effective and efficient. Commenters who supported eliminating the IPO list maintained that the existence of the IPO list did not impact the quality of care beneficiaries receive as there is no distinction between inpatient and outpatient care. Specifically, a few commenters insisted that, for most hospitals the IPO list has no impact on the quality of care provided: Procedures are done in the same operating rooms, with the same infrastructure and the same staff. One commenter asserted that it is an inaccurate conclusion that the provision of services is less safe when conducted in an hospital outpatient setting. The commenter argued that no data has been provided to demonstrate that the removal of services from the IPO list in 2021 resulted in higher incidences of adverse events or increased risk to patient safety when performed in the hospital outpatient setting. Another commenter requested clarification on why CMS believes the IPO list is in the best interest of patient safety. The commenter stated that while there may be enhanced safety for surgeries performed in a hospital versus an ASC or physician office, it is unclear how patient safety differs between the hospital inpatient and hospital outpatient settings. They claimed that utilization of outpatient services

increased across all plan types with the 2021 elimination of the IPO list, highlighting the impact across the healthcare system. The commenter noted high levels of patient satisfaction and no compromise in quality as measured by unplanned returns to the emergency department or operating room and no readmissions following services performed in the hospital outpatient setting. Several commenters acknowledged that there will be patients for whom an inpatient procedure remains the safest and most clinically appropriate option but believed that there should be additional flexibility for Medicare beneficiaries who meet relevant clinical criteria. In addition, one commenter suggested that the elimination of the IPO list should occur over 5 to 7 instead of 3.

Response: We appreciate the commenter's feedback. We again acknowledge commenters' concerns regarding the administrative and operational challenges associated with the IPO list, including the application of the 2-midnight benchmark to services that are removed from the IPO list. In addition to the mechanisms that are already in place, including the case-by-case exceptions to the 2-midnight benchmark and the exemption from certain medical review activities related to the 2-midnight rule for procedures that have been recently removed from the IPO list, CMS will continue to work with stakeholders to address these operational concerns in future rulemaking. We again refer readers to section X. of this final rule with comment period for additional discussion regarding the 2-midnight rule.

We also acknowledge stakeholders' concerns regarding the lack of definitive data that shows a difference between services performed in the inpatient and outpatient settings. In the absence of data demonstrating that these procedures can be safely furnished to the typical Medicare beneficiary in the hospital outpatient setting we continue to believe that it is necessary to prioritize the potential impact that removing services from the IPO list has on beneficiary safety and quality of care and develop additional ways to monitor safety prior to removing such a large number of services from the IPO list. We note that certain commenters in this rulemaking cycle (and past OPPS rules) have indicated that hospitals and other payers may use the circumstance of CMS removing a service from the IPO list to encourage that service to be performed outpatient, even when not clinically appropriate for the patient, and we remain concerned about these potential spillover effects due to changes in our policy. As described above, we also believe that the policy to eliminate the IPO list transpired quickly, and we believe it is necessary to halt the elimination of the IPO list and reinstate a more measured process of separately evaluating the inpatient only classification of each service against the five longstanding criteria.

We also note and appreciate commenters concerns about the varying clinical appropriateness of furnishing a given service in the hospital outpatient setting based on a beneficiary's clinical status; that is, we acknowledge that it may be appropriate to furnish certain services in the hospital outpatient setting for a certain number of beneficiaries due to their clinical circumstances, while at the same time it may not be appropriate to furnish those same services in the hospital outpatient setting for many other beneficiaries. As stated in the CY 2022 OPPS/ASC proposed rule, we continue to believe that physicians should use their complex clinical judgment, together with consideration of the beneficiary's needs, to determine the appropriate site of service. We continue to strive to balance the goals of increasing physician and patient choice of setting of care with consideration of patient safety for all Medicare beneficiaries.

After consideration of the comments, we are finalizing our proposal without modification to halt the elimination of the IPO list. In accordance with this proposal, we are finalizing our proposal to amend the regulation at § 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a 3-year transition.

We refer readers to section IX.B.3 of this final rule with comment period for a discussion on the services removed in CY 2021 that we proposed to return to the IPO list in CY 2022.

2. Proposal To Codify Longstanding Criteria

As we stated in the CY 2022 OPPS/ASC proposed rule, we continue to believe that physicians must use their complex clinical judgment, together with consideration of the beneficiary's needs, to determine the appropriate site of service, but we explained that the broad removal of services from the IPO list in CY 2021 did not allow us to assess whether procedures proposed for removal met the longstanding removal criteria that we have historically used in consideration of the typical Medicare beneficiary. As discussed above and in the proposed rule, to ensure beneficiary safety, we have historically used longstanding criteria to determine if a procedure should be removed from the IPO list, but we noted that the procedures removed from the IPO list beginning in CY 2021 were not assessed against these criteria because we adopted a policy to eliminate the IPO list entirely. After further consideration, we explained that we believe it is important to continue to assess whether services individually meet any of the criteria for removal from the IPO list before being removed. In the CY 2022 OPPS/ASC proposed rule, we proposed to codify in the regulation text in a new § 419.23 our five longstanding criteria, listed above, for determining whether a service or procedure should be removed from the IPO list.

Comment: A majority of commenters, including hospital systems, medical specialty societies, and professional organizations, supported our proposal to codify the five longstanding criteria to determine if a procedure should be removed from the IPO list and supported using the criteria to evaluate the 298 procedures removed from the IPO list in the CY 2021 OPPS/ASC final rule with comment period. Many commenters supported the criteria as proposed, stating that the longstanding criteria appropriately reflect progress and allow us to efficiently assess if outpatient departments are equipped to provide the services under consideration for removal.

Response: We thank commenters for their support.

Comment: Some commenters suggested modifications to the five proposed criteria. One commenter requested that CMS modify the first two criteria to change ''most outpatient departments'' to ''outpatient departments conducting surgical procedures,'' due to concerns that the proposed language is undefined and vague. The commenter also expressed that our third criterion—that the procedure is related to codes that we have already removed from the IPO list—was limiting and should be modified to address codes that do not have related codes being considered for removal from the IPO list. We also received comments requesting that we modify the fourth criterion (a determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis) to further define ''outpatient basis'' and ''numerous''. We also received a comment citing concerns that many hospitals do submit claims to Medicare for procedures on the IPO list when they are performed in the hospital outpatient setting due to lack of payment. We also received two

comments requesting that we remove the fifth criterion due to concerns that CMS is comparing the capabilities and safety of performing a service in the ASC setting to that of the hospital setting, noting that hospitals have greater resources and are able to admit patients if complications arise.

Further, a few commenters believed our longstanding pre-2021 policy of requiring a service to meet only one criterion to be removed from the IPO list was too lenient and prevented stakeholders from anticipating when a procedure would be eligible for removal from the IPO list. The commenters recommended that we require services to meet all five criteria in order to be removed from the IPO list.

Response: We appreciate the commenters' recommendations and will consider them for future rulemaking. Due in part to the overwhelming support we received from commenters to codify in regulation the current five criteria as well as our position that the criteria remain appropriate, we do not believe it is necessary to change them at this time. However, we plan to continue to engage stakeholders and consider feedback on modifications to the criteria.

As we stated in previous rulemaking, we created the first three criteria because we identified services that were often safely performed in the hospital outpatient setting based on comments we received. We also identified additional services where the simplest procedure described by the code may be performed safely in the hospital outpatient setting or that they were related to codes we removed from the IPO list (65 FR 18456). We established the fourth and fifth criteria in later rulemaking after identifying procedures that were on the IPO list but were also being performed on an outpatient basis or being safely and appropriately performed in the ASC setting (67 FR 66741). These criteria were created to ensure consistency between the IPO list and the ASC CPL and to identify services that are included on the ASC CPL, and therefore should be removed from the IPO list. These criteria were created to help independently identify procedures that could be appropriately performed in the hospital outpatient setting and we reiterate that a service does not need to meet all of the criteria to be removed from the IPO list, meaning that a service does not need to have related codes already removed from the IPO list or does not need to be safely furnished in the ASC setting to be removed from the IPO list.

Additionally, we do not believe that our policy to only require a service to meet one criterion to be removed from the IPO list is too lenient. We believe that not requiring a service to meet multiple criteria allows for greater flexibility to determine if a service is appropriate to remove from the IPO list, as some criteria are irrelevant to certain services. As stated above, while we only require a service to meet one criterion to be considered for removal, satisfying only one criterion does not guarantee that the service will be removed, instead, the case for removal is strengthened with the more criteria the service meets.

Comment: Commenters also recommended additional criteria as well as methods of evaluating the five existing criteria. We also received multiple comments recommending that criteria used to determine if a service is appropriate to remove from the IPO list should consider clinical factors and social factors, including patient's age and comorbidities, support systems, access to care, health literacy, prior hospitalizations, and functional status. Numerous commenters stressed that without consideration of clinical and social factors, patients, surgeons, and hospitals in underserved communities could bear a disproportionate burden and experience unintended consequences of more services being payable in the hospital outpatient setting. Commenters recommended that we also evaluate the out-of-pocket financial impact that moving a service to the hospital outpatient setting would have on Medicare beneficiaries.

Commenters suggested that changes to the IPO list should be based upon scientific evidence on safety, quality, and advancements in medical technology. They acknowledged that a majority of inpatient procedures have limited or no evidence on the safety of performing them in the hospital outpatient setting and that at least some of the evidence available is based on limited, incomplete, or conflicting data from other claims.

We also received some comments with recommendations regarding the data that CMS uses for evaluating services on the IPO list. We received several comments suggesting that CMS analyze claims data for services that had a stay less than 2-midnights and use this data to determine if a service should be eligible to be paid when furnished in the hospital outpatient setting. One commenter also requested that CMS clarify how different data, including commercial data, would be considered when evaluating services for removal using the five criteria as the general patient population used in the collection of the data may vary from the Medicare population.

One commenter urged CMS not to use billed and denied outpatient claims as a source of data to determine if hospitals are equipped to provide a service in the hospital outpatient setting. The commenter advised that there would be few outpatient claims for services on the IPO list because hospitals would avoid billing claims that would be denied. The commenter suggested that CMS should instead analyze the geometric mean or median length of stay for IPPS claims reported with procedures on the IPO list, and crosswalk the ICD–10–PCS codes on the IPPS claims to the CPT codes on the IPO list, so that CMS could analyze data where the patient would remain in the hospital post-procedure, but require less time, less intensive care, or pose less risk than the typical hospital inpatient. The commenter also suggested that CMS analyze data on short-stay inpatient hospitalizations from the Beneficiary Family Centered Care-Quality Improvement Organizations (BFCC–QIOs), with the QIOs nominating procedures that they commonly see in their reviews. Finally, we also received comments recommending that CMS work closely with stakeholders and providers and consider their feedback when evaluating services on the IPO list against our criteria, and to allow for the consideration of factors in addition to the five criteria.

Response: We appreciate the commenters' recommendations. We note that we take clinical evidence into consideration when evaluating a service for removal from the IPO list. We also consider all other available data, including outpatient, inpatient, and professional claims data. This includes data on length-of-stay, and we have continuously encouraged stakeholders to bring decreasing length-of-stays and successful same day discharges to our attention to aid our review (65 FR 18456). We agree that there are limitations in the studies and data available to aid our assessment of the appropriateness of removing procedures from the IPO list, particularly studies that compare outcomes for services furnished in the inpatient hospital setting versus the outpatient hospital setting as well as studies that analyze outcomes for the typical Medicare beneficiary. More specifically, while studies may demonstrate safety for a given procedure in the outpatient hospital setting, those studies may not focus on a Medicare-aged population, or involve patients with certain comorbid conditions that are common for patients 65 and older. We continue to explore

ways to engage stakeholders to effectively address limitations in these studies, and we look forward to future work on these important issues. We reiterate that we do not believe it is appropriate at this time to modify the criteria, which were overwhelmingly supported by commenters, as we reinstate and codify them in regulation text. However, as previously stated, we will continue to engage stakeholders and consider feedback on modifications to the criteria for removal from the IPO list.

Comment: One commenter opposed codifying the five longstanding criteria and expressed concern that codifying the criteria would delay timely updates to the IPO. The commenter was concerned that the process of submitting a request to add or remove a service and providing evidence, including peer-reviewed medical literature, physician comments, and outcome data, is time consuming and may cause unnecessary delays in hospitals' ability to provide care and be paid under the OPPS when services are furnished in the hospital outpatient setting for beneficiaries for whom the services are clinically appropriate.

Response: We appreciate the commenter's response. We believe that using our five criteria to evaluate services for removal from the IPO list is necessary to ensure OPPS payment is available for services that are safe for the typical Medicare beneficiary to receive in the hospital outpatient setting. We also believe that the comments and evidence we receive are an important aspect of determining whether it is appropriate to remove a service from the IPO list. Because we review requests to add or remove services from the IPO list annually and address those removals or additions in notice-and-comment rulemaking, we do not believe that use of criteria to assess whether procedures should be removed causes unnecessary delays in making payment available for appropriate procedures under the OPPS.

After reviewing the public comments we received we are finalizing our proposal without modification to codify our five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation text in a new § 419.23.

3. Returning Procedures Removed in CY 2021 to the IPO List for CY 2022

As discussed earlier in section IX.A. of this final rule with comment period, we typically evaluate whether a service should be removed from the IPO list using five criteria and, while a service does not need to meet all of the criteria to be removed from the IPO list, it should meet at least one criterion, with the case for removing the service from the IPO list strengthened with the more criteria the service meets. For CY 2021, in light of our proposal to eliminate the IPO list over a three-year transition, we proposed that musculoskeletal services would be the first group of services removed from the IPO list. We stated that we proposed to remove this group of services first for several reasons. In recent years, due to new technologies and advances in surgical care protocols, expedited rehabilitation protocols, and significant enhancements in postoperative processes, we have removed TKA and THA, which are both musculoskeletal services, from the IPO list. During the process of proposing and finalizing removing TKA and THA from the IPO list, stakeholders have continuously requested that CMS remove other musculoskeletal services from the IPO list as well, citing shortened length of stay times, advancements in technologies and surgical techniques, and improved postoperative processes. Additionally, we noted that, more often than not, stakeholders historically requested that we remove musculoskeletal services from the IPO list more than other types of services. We also recognized that there is already a set of comprehensive APCs for musculoskeletal services for payment under the OPPS, which facilitates payment for these services and further supported their removal for CY 2021. Specifically, because we had previously removed codes from the IPO list that are similar clinically and in terms of resource cost and assigned them to these comprehensive APCs, we explained that these APCs generally describe appropriate ranges for the musculoskeletal codes removed in CY 2021, which we believed allowed for appropriate payment. We also proposed to remove additional related services that were recommended for removal by stakeholders during the annual HOP panel meeting. As stated above, because these services were being removed from the IPO list as the first phase of the elimination of the list, we did not evaluate each of these services against the longstanding criteria for removing a service from the IPO list.

During the 2021 rulemaking process, a number of commenters supported the removal of the 298 services, but the vast majority of commenters were opposed to removing the services and shared concerns regarding their inability to properly review the clinical nature of this large number of procedures and to provide comprehensive feedback on their removal from the list. Some commenters were able to review the individual services and requested that specific CPT codes remain payable in the inpatient setting only, including CPT codes 27280 (Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed) and 22857 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar) due to concerns about the safety of these procedures if they are performed in the hospital outpatient setting.

As previously stated in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86087), an overwhelming number of stakeholders supported the previously established methodology for identifying appropriate changes to the IPO list. CMS received numerous requests to continue to use the established criteria to review and analyze services proposed for removal as opposed to removing large numbers of services in groups or categories. Commenters noted that they preferred the historical process for assessing services for removal from the IPO list using the five criteria, as they believed this process was more manageable for patients, providers, and other stakeholders, allowing them to provide meaningful input on a procedure-by-procedure basis.

We stated in the CY 2022 OPPS/ASC proposed rule that because we proposed to halt elimination of the IPO list, we also believe it is appropriate to continue to evaluate services that we proposed for removal against the longstanding criteria, and include with our proposals an in-depth analysis of whether most outpatient departments are equipped to provide the services to the Medicare population; whether the simplest procedure described by the code may be performed in most outpatient departments; whether the procedure is related to codes that we have already removed from the IPO list; whether the procedure is being performed in numerous hospitals on an outpatient basis; and whether the procedure can be appropriately and safely performed in an ASC, is on the list of approved ASC procedures, or has been proposed by us for addition to the ASC list. Historically, we have included discussions of the individual codes proposed for removal in the proposed rule and stakeholders have had the opportunity to comment with evidence in support of or opposition to the service's assignment to the IPO list, and we believe it is appropriate to continue to do so.

Furthermore, we explained in the CY 2022 OPPS/ASC proposed rule that in light of ongoing stakeholder feedback, we reviewed each of the procedures removed from the IPO list in CY 2021 to determine whether they individually meet the longstanding criteria for removal from the list for CY 2022. Our review considered the clinical intensity and characteristics of the service, the underlying condition of the beneficiary who would require the service, peer-reviewed medical literature, case reports, clinical criteria sets, and utilization data. This initial review determined that none of the services removed in CY 2021 have sufficient supporting evidence that the service can be safely performed on the Medicare population in the hospital outpatient setting, that most outpatient departments are equipped to provide the services to the Medicare population, or that the services are being performed safely on an outpatient basis. For a large number of the removed services, we did not find vignettes, claims or utilization data, or literature to support their removal under our longstanding criteria. For the few services that did have some data supporting their removal from the list, we found the data to be either incomplete or to be countered by conflicting data. For example, a few services, including CPT code 21627 (sternal debridement), showed increasing migration to the hospital outpatient setting, but we could not locate supportive medical literature case studies or outcomes data to support that the services are safe for the Medicare population in the hospital outpatient setting. Some services, such as CPT code 22558 (Lumbar spine fusion) and CPT code 23472 (reconstruct shoulder joint), show increasing outpatient claims data, but have high length of stay times and extensive post-operative care needs that indicate these services may not be appropriate for the Medicare population in the hospital outpatient setting. Other services, such as CPT code 22846 (Anterior instrumentation; 4 to 7 vertebral segments), lack medical literature or case studies, lack supportive claims data, and have conflicting stakeholder feedback for the safety of the service in the hospital outpatient setting. We were unable to find literature and data for services that included outcomes specific to the Medicare population, particularly in the hospital outpatient setting.

We stated in the CY 2022 OPPS/ASC proposed rule that given that our initial review of each of the services removed from the list in CY 2021 using the five criteria mentioned in section IX.A. of this final rule with comment period did not find sufficient evidence that any of these services would be safe to perform on the Medicare population in the hospital outpatient setting, we did not believe it would be appropriate for Medicare to pay for these services when performed in a hospital outpatient setting. In particular, we found that the simplest procedures described by the codes for these services cannot be furnished safely in most outpatient departments, most outpatient departments are not equipped to provide these services to the Medicare population, and the procedures were not being performed in numerous hospitals on an outpatient basis. We also did not believe the services could be appropriately and safely furnished in an ASC. As a result of this review, we proposed to return all of the procedures removed in the CY 2021 OPPS/ASC final rule with comment period to the IPO list for CY 2022 because we did not believe they met the previously established criteria for removal from the IPO list. Therefore, after further clinical review and additional consideration of safety and quality of care concerns for the group of services removed from the IPO list in the CY 2021 final rule, for CY 2022 we proposed to return these 298 services to the IPO list, as shown in Table 45 below.

We solicited public comment on whether there are services that were removed from the IPO list in CY 2021 that stakeholders believe do meet the longstanding criteria for removing services from the IPO list and should continue to be payable in the hospital outpatient setting in CY 2022. If so, we requested that commenters submit corresponding evidence—including, but not limited to, case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols—that the service meets the longstanding criteria for removal from the IPO list and is safe to perform on the typical Medicare population in the hospital outpatient setting.

As mentioned above, the services that we proposed to add back to the IPO list reflect those services that we believe may pose increased safety risk to the typical Medicare beneficiary. However, we recognized that there may be a subset of Medicare beneficiaries who, on a case-by case-basis, may nonetheless be appropriate to treat in the hospital outpatient setting and we sought comment below on whether any services that were removed in CY 2021, but were proposed to be added back to the IPO for CY 2022, should in fact, remain off the IPO list. Table 45 below contains the proposed additions to the IPO list for CY 2022.

BILLING CODE 4120–01–P

TABLE 45: PROPOSED ADDITIONS TO THE INPATIENT ONLY (IPO) LIST FOR CY 2022

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
00192	Anesthesia for procedures on facial bones or skull; radical surgery (including prognathism)	C
00474	Anesthesia for partial rib resection; radical procedures (e.g., pectus excavatum)	C
00604	Anesthesia for procedures on cervical spine and cord; procedures with patient in the sitting position	C
00904	Anesthesia for; radical perineal procedure	C
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	C
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	C
01140	Anesthesia for interpelviabdominal (hindquarter) amputation	C
01150	Anesthesia for radical procedures for tumor of pelvis, except hindquarter amputation	C
01212	Anesthesia for open procedures involving hip joint; hip disarticulation	C
01232	Anesthesia for open procedures involving upper two-thirds of femur; amputation	C
01234	Anesthesia for open procedures involving upper two-thirds of femur; radical resection	C
01274	Anesthesia for procedures involving arteries of upper leg, including bypass graft; femoral artery embolectomy	C
01404	Anesthesia for open or surgical arthroscopic procedures on knee joint; disarticulation at knee	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
01486	Anesthesia for open procedures on bones of lower leg, ankle, and foot; total ankle replacement	C
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (list separately in addition to code for primary procedure)	C
01634	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; shoulder disarticulation	C
01636	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; interthoracoscapular (forequarter) amputation	C
01638	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; total shoulder replacement	C
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	C
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	C
01756	Anesthesia for open or surgical arthroscopic procedures of the elbow; radical procedures	C
0202T	Posterior vertebral joint(s) arthroplasty (for example, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine	C
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
0220T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic	C
20661	Application of halo, including removal; cranial	C
20664	Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (e.g., pediatric patients, hydrocephalus, osteogenesis imperfecta)	C
20802	Replantation, arm (includes surgical neck of humerus through elbow joint), complete amputation	C
20805	Replantation, forearm (includes radius and ulna to radial carpal joint), complete amputation	C
20808	Replantation, hand (includes hand through metacarpophalangeal joints), complete amputation	C
20816	Replantation, digit, excluding thumb (includes metacarpophalangeal joint to insertion of flexor sublimis tendon), complete amputation	C
20824	Replantation, thumb (includes carpometacarpal joint to MP joint), complete amputation	C
20827	Replantation, thumb (includes distal tip to MP joint), complete amputation	C
20838	Replantation, foot, complete amputation	C
20955	Bone graft with microvascular anastomosis; fibula	C
20956	Bone graft with microvascular anastomosis; iliac crest	C
20957	Bone graft with microvascular anastomosis; metatarsal	C
20962	Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal	C
20969	Free osteocutaneous flap with microvascular anastomosis; other than iliac crest, metatarsal, or great toe	C
20970	Free osteocutaneous flap with microvascular anastomosis; iliac crest	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
21045	Excision of malignant tumor of mandible; radical resection	C
21141	Reconstruction midface, lefort i; single piece, segment movement in any direction (for example, for long face syndrome), without bone graft	C
21142	Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft	C
21143	Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft	C
21145	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	C
21146	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	C
21147	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	C
21151	Reconstruction midface, LeFort II; any direction, requiring bone grafts (includes obtaining autografts)	C
21154	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); without LeFort I	C
21155	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); with LeFort I	C
21159	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); without LeFort I	C
21160	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); with LeFort I	C
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)	C
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
21182	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting less than 40 sq cm	C
21183	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 40 sq cm but less than 80 sq cm	C
21184	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 80 sq cm	C
21188	Reconstruction midface, osteotomies (other than lefort type) and bone grafts (includes obtaining autografts)	C
21194	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)	C
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	C
21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (for example, for hemifacial microsomia)	C
21255	Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts)	C
21268	Orbital repositioning, periorbital osteotomies, unilateral, with bone grafts; combined intra- and extracranial approach	C
21343	Open treatment of depressed frontal sinus fracture	C
21344	Open treatment of complicated (for example, comminuted or involving posterior wall) frontal sinus fracture, via coronal or multiple approaches	C
21347	Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
21348	Open treatment of nasomaxillary complex fracture (lefort ii type); with bone grafting (includes obtaining graft)	C
21366	Open treatment of complicated (for example, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)	C
21422	Open treatment of palatal or maxillary fracture (lefort i type);	C
21423	Open treatment of palatal or maxillary fracture (lefort i type); complicated (comminuted or involving cranial nerve foramina), multiple approaches	C
21431	Closed treatment of craniofacial separation (lefort iii type) using interdental wire fixation of denture or splint	C
21432	Open treatment of craniofacial separation (lefort iii type); with wiring and/or internal fixation	C
21433	Open treatment of craniofacial separation (lefort iii type); complicated (for example, comminuted or involving cranial nerve foramina), multiple surgical approaches	C
21435	Open treatment of craniofacial separation (lefort iii type); complicated, utilizing internal and/or external fixation techniques (for example, head cap, halo device, and/or intermaxillary fixation)	C
21436	Open treatment of craniofacial separation (lefort iii type); complicated, multiple surgical approaches, internal fixation, with bone grafting (includes obtaining graft)	C
21510	Incision, deep, with opening of bone cortex (for example, for osteomyelitis or bone abscess), thorax	C
21602	Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy	C
21603	Excision of chest wall tumor involving rib(s), with plastic reconstruction; with mediastinal lymphadenectomy	C
21615	Excision first and/or cervical rib;	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
21616	Excision first and/or cervical rib; with sympathectomy	C
21620	Ostectomy of sternum, partial	C
21627	Sternal debridement	C
21630	Radical resection of sternum;	C
21632	Radical resection of sternum; with mediastinal lymphadenectomy	C
21705	Division of scalenus anticus; with resection of cervical rib	C
21740	Reconstructive repair of pectus excavatum or carinatum; open	C
21750	Closure of median sternotomy separation with or without debridement (separate procedure)	C
21825	Open treatment of sternum fracture with or without skeletal fixation	C
22010	Incision and drainage, open, of deep abscess (subfascial), posterior spine; cervical, thoracic, or cervicothoracic	C
22015	Incision and drainage, open, of deep abscess (subfascial), posterior spine; lumbar, sacral, or lumbosacral	C
22110	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; cervical	C
22112	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; thoracic	C
22114	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar	C
22116	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
22206	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); thoracic	C
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); lumbar	C
22208	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); each additional vertebral segment (list separately in addition to code for primary procedure)	C
22210	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical	C
22212	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic	C
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar	C
22216	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (list separately in addition to primary procedure)	C
22220	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; cervical	C
22222	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic	C
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	C
22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	C
22318	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; without grafting	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
22319	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; with grafting	C
22325	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; lumbar	C
22326	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; cervical	C
22327	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; thoracic	C
22328	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; each additional fractured vertebra or dislocated segment (list separately in addition to code for primary procedure)	C
22532	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	C
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	C
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (list separately in addition to code for primary procedure)	C
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-c1-c2 (atlas-axis), with or without excision of odontoid process	C
22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	C
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, l5-s1 interspace	C
22590	Arthrodesis, posterior technique, craniocervical (occiput-c2)	C
22595	Arthrodesis, posterior technique, atlas-axis (c1-c2)	C
22600	Arthrodesis, posterior or posterolateral technique, single level; cervical below c2 segment	C
22610	Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral transverse technique, when performed)	C
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)	C
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments	C
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments	C
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments	C
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments	C
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments	C
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments	C
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments	C
22830	Exploration of spinal fusion	C
22841	Internal spinal fixation by wiring of spinous processes (list separately in addition to code for primary procedure)	C
22843	Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (list separately in addition to code for primary procedure)	C
22844	Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (list separately in addition to code for primary procedure)	C
22846	Anterior instrumentation; 4 to 7 vertebral segments (list separately in addition to code for primary procedure)	C
22847	Anterior instrumentation; 8 or more vertebral segments (list separately in addition to code for primary procedure)	C
22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (list separately in addition to code for primary procedure)	C
22849	Reinsertion of spinal fixation device	C
22850	Removal of posterior nonsegmental instrumentation (for example, harrington rod)	C
22852	Removal of posterior segmental instrumentation	C
22855	Removal of anterior instrumentation	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar	C
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	C
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	C
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	C
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	C
23200	Radical resection of tumor; clavicle	C
23210	Radical resection of tumor; scapula	C
23220	Radical resection of tumor, proximal humerus	C
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (for example, total shoulder)	C
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	C
23900	Interthoracoscapular amputation (forequarter)	C
23920	Disarticulation of shoulder;	C
24900	Amputation, arm through humerus; with primary closure	C
24920	Amputation, arm through humerus; open, circular (guillotine)	C
24930	Amputation, arm through humerus; re-amputation	C
24931	Amputation, arm through humerus; with implant	C
24940	Cineplasty, upper extremity, complete procedure	C
25900	Amputation, forearm, through radius and ulna;	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
25905	Amputation, forearm, through radius and ulna; open, circular (guillotine)	C
25915	Krukenberg procedure	C
25920	Disarticulation through wrist;	C
25924	Disarticulation through wrist; re-amputation	C
25927	Transmetacarpal amputation;	C
26551	Transfer, toe-to-hand with microvascular anastomosis; great toe wrap-around with bone graft	C
26553	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, single	C
26554	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, double	C
26556	Transfer, free toe joint, with microvascular anastomosis	C
26992	Incision, bone cortex, pelvis and/or hip joint (for example, osteomyelitis or bone abscess)	C
27005	Tenotomy, hip flexor(s), open (separate procedure)	C
27025	Fasciotomy, hip or thigh, any type	C
27030	Arthrotomy, hip, with drainage (for example, infection)	C
27036	Capsulectomy or capsulotomy, hip, with or without excision of heterotopic bone, with release of hip flexor muscles (ie, gluteus medius, gluteus minimus, tensor fascia latae, rectus femoris, sartorius, iliopsoas)	C
27054	Arthrotomy with synovectomy, hip joint	C
27070	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); superficial	C
27071	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); deep (subfascial or intramuscular)	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
27075	Radical resection of tumor; wing of ilium, 1 pubic or ischial ramus or symphysis pubis	C
27076	Radical resection of tumor; ilium, including acetabulum, both pubic rami, or ischium and acetabulum	C
27077	Radical resection of tumor; innominate bone, total	C
27078	Radical resection of tumor; ischial tuberosity and greater trochanter of femur	C
27090	Removal of hip prosthesis; (separate procedure)	C
27091	Removal of hip prosthesis; complicated, including total hip prosthesis, methylmethacrylate with or without insertion of spacer	C
27120	Acetabuloplasty; (for example, whitman, colonna, haygroves, or cup type)	C
27122	Acetabuloplasty; resection, femoral head (for example, girdlestone procedure)	C
27125	Hemiarthroplasty, hip, partial (for example, femoral stem prosthesis, bipolar arthroplasty)	C
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	C
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	C
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	C
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft	C
27140	Osteotomy and transfer of greater trochanter of femur (separate procedure)	C
27146	Osteotomy, iliac, acetabular or innominate bone;	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
27147	Osteotomy, iliac, acetabular or innominate bone; with open reduction of hip	C
27151	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy	C
27156	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy and with open reduction of hip	C
27158	Osteotomy, pelvis, bilateral (for example, congenital malformation)	C
27161	Osteotomy, femoral neck (separate procedure)	C
27165	Osteotomy, intertrochanteric or subtrochanteric including internal or external fixation and/or cast	C
27170	Bone graft, femoral head, neck, intertrochanteric or subtrochanteric area (includes obtaining bone graft)	C
27175	Treatment of slipped femoral epiphysis; by traction, without reduction	C
27176	Treatment of slipped femoral epiphysis; by single or multiple pinning, in situ	C
27177	Open treatment of slipped femoral epiphysis; single or multiple pinning or bone graft (includes obtaining graft)	C
27178	Open treatment of slipped femoral epiphysis; closed manipulation with single or multiple pinning	C
27181	Open treatment of slipped femoral epiphysis; osteotomy and internal fixation	C
27185	Epiphyseal arrest by epiphysiodesis or stapling, greater trochanter of femur	C
27187	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate, femoral neck and proximal femur	C
27222	Closed treatment of acetabulum (hip socket) fracture(s); with manipulation, with or without skeletal traction	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
27226	Open treatment of posterior or anterior acetabular wall fracture, with internal fixation	C
27227	Open treatment of acetabular fracture(s) involving anterior or posterior (one) column, or a fracture running transversely across the acetabulum, with internal fixation	C
27228	Open treatment of acetabular fracture(s) involving anterior and posterior (two) columns, includes t-fracture and both column fracture with complete articular detachment, or single column or transverse fracture with associated acetabular wall fracture, with internal fixation	C
27232	Closed treatment of femoral fracture, proximal end, neck; with manipulation, with or without skeletal traction	C
27236	Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	C
27240	Closed treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with manipulation, with or without skin or skeletal traction	C
27244	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with plate/screw type implant, with or without cerclage	C
27245	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with intramedullary implant, with or without interlocking screws and/or cerclage	C
27248	Open treatment of greater trochanteric fracture, includes internal fixation, when performed	C
27253	Open treatment of hip dislocation, traumatic, without internal fixation	C
27254	Open treatment of hip dislocation, traumatic, with acetabular wall and femoral head fracture, with or without internal or external fixation	C
27258	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc);	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
27259	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc); with femoral shaft shortening	C
27268	Closed treatment of femoral fracture, proximal end, head; with manipulation	C
27269	Open treatment of femoral fracture, proximal end, head, includes internal fixation, when performed	C
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed	C
27282	Arthrodesis, symphysis pubis (including obtaining graft)	C
27284	Arthrodesis, hip joint (including obtaining graft);	C
27286	Arthrodesis, hip joint (including obtaining graft); with subtrochanteric osteotomy	C
27290	Interpelviabdominal amputation (hindquarter amputation)	C
27295	Detachment of hip joint	C
27303	Incision, deep, with opening of bone cortex, femur or knee (for example, osteomyelitis or bone abscess)	C
27365	Radical resection of tumor, femur or knee	C
27445	Arthroplasty, knee, hinge prosthesis (for example, walldius type)	C
27448	Osteotomy, femur, shaft or supracondylar; without fixation	C
27450	Osteotomy, femur, shaft or supracondylar; with fixation	C
27454	Osteotomy, multiple, with realignment on intramedullary rod, femoral shaft (for example, sofield type procedure)	C
27455	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); before epiphyseal closure	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
27457	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); after epiphyseal closure	C
27465	Osteoplasty, femur; shortening (excluding 64876)	C
27466	Osteoplasty, femur; lengthening	C
27468	Osteoplasty, femur; combined, lengthening and shortening with femoral segment transfer	C
27470	Repair, nonunion or malunion, femur, distal to head and neck; without graft (for example, compression technique)	C
27472	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	C
27486	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	C
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component	C
27488	Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee	C
27495	Prophylactic treatment (nailing, pinning, plating, or wiring) with or without methylmethacrylate, femur	C
27506	Open treatment of femoral shaft fracture, with or without external fixation, with insertion of intramedullary implant, with or without cerclage and/or locking screws	C
27507	Open treatment of femoral shaft fracture with plate/screws, with or without cerclage	C
27511	Open treatment of femoral supracondylar or transcondylar fracture without intercondylar extension, includes internal fixation, when performed	C
27513	Open treatment of femoral supracondylar or transcondylar fracture with intercondylar extension, includes internal fixation, when performed	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
27514	Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	C
27519	Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	C
27535	Open treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed	C
27536	Open treatment of tibial fracture, proximal (plateau); bicondylar, with or without internal fixation	C
27540	Open treatment of intercondylar spine(s) and/or tuberosity fracture(s) of the knee, includes internal fixation, when performed	C
27556	Open treatment of knee dislocation, includes internal fixation, when performed; without primary ligamentous repair or augmentation/reconstruction	C
27557	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	C
27558	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	C
27580	Arthrodesis, knee, any technique	C
27590	Amputation, thigh, through femur, any level;	C
27591	Amputation, thigh, through femur, any level; immediate fitting technique including first cast	C
27592	Amputation, thigh, through femur, any level; open, circular (guillotine)	C
27596	Amputation, thigh, through femur, any level; re-amputation	C
27598	Disarticulation at knee	C
27645	Radical resection of tumor; tibia	C
27646	Radical resection of tumor; fibula	C
27703	Arthroplasty, ankle; revision, total ankle	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
27712	Osteotomy; multiple, with realignment on intramedullary rod (for example, sofield type procedure)	C
27715	Osteoplasty, tibia and fibula, lengthening or shortening	C
27724	Repair of nonunion or malunion, tibia; with iliac or other autograft (includes obtaining graft)	C
27725	Repair of nonunion or malunion, tibia; by synostosis, with fibula, any method	C
27727	Repair of congenital pseudarthrosis, tibia	C
27880	Amputation, leg, through tibia and fibula;	C
27881	Amputation, leg, through tibia and fibula; with immediate fitting technique including application of first cast	C
27882	Amputation, leg, through tibia and fibula; open, circular (guillotine)	C
27886	Amputation, leg, through tibia and fibula; re-amputation	C
27888	Amputation, ankle, through malleoli of tibia and fibula (for example, syme, pirogoff type procedures), with plastic closure and resection of nerves	C
28800	Amputation, foot; midtarsal (for example, chopart type procedure)	C
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral	C
35800	Exploration for postoperative hemorrhage, thrombosis or infection; neck	C
37182	Insertion of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract formation/dilatation, stent placement and all associated imaging guidance and documentation)	C
37617	Ligation, major artery (eg, post-traumatic, rupture); abdomen	C
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury	C
44300	Placement, enterostomy or cecostomy, tube open (eg, for feeding or decompression) (separate procedure)	C
44314	Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)	C
44345	Revision of colostomy; complicated (reconstruction in-depth) (separate procedure)	C
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)	C
44602	Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture; single perforation	C
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)	C
49255	Omentectomy, epiploectomy, resection of omentum (separate procedure)	C
51840	Anterior vesicourethropexy, or urethropexy (eg, marshall-marchetti-krantz, burch); simple	C
56630	Vulvectomy, radical, partial;	C
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)	C
G0412	Open treatment of iliac spine(s), tuberosity avulsion, or iliac wing fracture(s), unilateral or bilateral for pelvic bone fracture patterns which do not disrupt the pelvic ring includes internal fixation, when performed	C
G0414	Open treatment of anterior pelvic bone fracture and/or dislocation for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation when performed (includes pubic symphysis and/or superior/inferior rami)	C

CY 2022 CPT Code	CY 2022 Long Descriptor	CY 2022 OPPS Proposed Status Indicator
G0415	Open treatment of posterior pelvic bone fracture and/or dislocation, for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation, when performed (includes ilium, sacroiliac joint and/or sacrum)	C

BILLING CODE 4120–01–C

Comment: Most comments supported returning all 298 services back to the IPO list for 2022. Of those commenters that supplied a rationale for their support for returning all 298 services to the IPO list, the most frequently cited reasons were the commenters' concerns with the pace that this shift would take place; the lack of data and evidence available to support furnishing these services in the hospital outpatient setting for the typical Medicare beneficiary; CMS' inability to monitor the impact of such a large migration of services from the inpatient setting to the hospital outpatient setting; CMS' inability to monitor patient safety outcomes for the services if furnished in the hospital outpatient setting; and that the PHE has impacted the commenters' ability to prepare for this shift. Commenters also expressed concerns regarding how quickly a large number of services were removed from the IPO list. Emphasizing the financial and clinical resources needed to prepare clear criteria for surgical site selection; develop criteria for patient selection; update their billing systems; and gain experience with furnishing newly removed services, commenters requested that CMS provide additional time in between removing services from the IPO list.

Response: We thank commenters for their support for our proposal to return 298 services to the IPO list, and their detailed feedback regarding their concerns about patient safety and the timeline for transitioning services off of the IPO list.

Comment: Some commenters opposed returning all 298 services to the IPO list and believed that if all 298 services are moved back on the IPO list in CY 2022, beneficiaries would receive care in an unnecessarily high-cost inpatient setting and experience higher out-of-pocket costs for services. In addition, they argued that higher costs coupled with potential delays in returning home will cause beneficiary dissatisfaction and increase overall cost to the healthcare system. One commenter stated that policy changes over the past 2 years have burdened facilities and clinicians. The commenter noted that many inpatient procedures are canceled due to the PHE, adding additional delays and negatively affecting patient experience and health. For these reasons the commenter suggested CMS reassess returning all 298 procedures to the IPO list.

Some commenters expressed concerns regarding outpatient surgeries for procedures we are returning to the IPO list that were scheduled prior to the publication of the final rule and the subsequent impact on beneficiaries when these surgeries are cancelled or payment is not available for them under the OPPS. Commenters requested that in the event the policy is finalized as proposed, CMS allow services scheduled as outpatient prior to the final rule's implementation date to be payable as they believe this would decrease provider burden and minimize impact on patients expecting outpatient care. The commenters stated that it is difficult for facilities and clinicians to invest in new equipment and develop protocols to move new procedures to the outpatient department if they are unsure how long services will remain payable in the hospital outpatient setting.

Response: We thank commenters for their support and for detailing their experiences. We recognize that there may be operational changes (including scheduling and other administrative changes) that may be necessary to adjust to our final policy to return services to the IPO list. We also recognize that the PHE has broadly impacted access to hospital services and note that we have taken several steps to broaden access to care during the PHE through rulemaking and through waivers issued using our authority in section 1135 of the Act. For additional information about the actions taken to expand access to care and otherwise address the PHE for COVID–19, please visit: *https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers*. However, we continue to share concerns expressed by other commenters regarding the speed at which we implemented this policy change. We believe that we need to reinstate a more measured process of evaluating individual services for removal from the IPO list against the five longstanding criteria, and to prioritize the potential impacts on the quality and safety of care for services when they are removed from the IPO list.

Comment: Certain commenters (mainly specialists and medical associations) requested specific services (roughly 120 services in total, ranging in complexity) not be placed back on the IPO list. Those services are listed in Table 46 below. These commenters indicated that they were currently performing some of these procedures on an outpatient basis in both the HOPD and ASC setting on non-Medicare patients.

Of those approximately 120 services requested to remain off of the IPO list, two stakeholders included supportive information for CPT 22630 (Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar); CPT 23472 (Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (for example, total shoulder))); and CPT 27702 (Arthroplasty, ankle; with implant (total ankle). Several commenters, including medical associations, specialty groups, and surgeons suggested that shoulder and ankle replacement surgeries performed in HOPDs and ASCs demonstrated optimal clinical outcomes. Commenters submitted several peer-reviewed studies

comparing outcomes for CPT 23472 and CPT 27702 performed in the inpatient versus the hospital outpatient setting. As a result, they believed performing CPT 23472 and CPT 27702 in a hospital outpatient setting is appropriate as determined by the treating health care provider. Some commenters cited all payer claims data and stated that, following the removal of services from the IPO list, nearly half of shoulder replacement surgeries were performed in the hospital outpatient setting in the first few months of 2021. Commenters that supported leaving CPT 23472 and CPT 27702 off the IPO list and payable under the OPPS highlighted that other procedures that were removed from the IPO list in CY 2021 did not demonstrate similar utilization in the hospital outpatient setting. The commenters stated that low utilization of the majority of services removed from the IPO in CY 2021 confirms physicians are using clinical judgment to determine when the hospital outpatient setting is clinically appropriate.

In regards to CPT 22630, a commenter noted that CPT codes 22633 (Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar) and 22612 (Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed), which are not on the IPO list, are performed with CPT code 22630 when a posterior approach 360-degree spinal fusion is performed. The commenter noted that while CPT code 22633 was removed from the IPO list in 2020 (84 FR 61355 through 61357), the service described by CPT code 22630, if added to the IPO list, will in effect make the combined procedure, described by CPT codes 22630 and 22633, unable to be performed in the outpatient hospital setting because both procedures need to be payable under the OPPS to be performed there. The commenter recommended keeping CPT code 22630 off the IPO list for CY 2022 so that the individual procedures, along with the combined procedure, are eligible for Medicare payment when furnished in the hospital outpatient setting for appropriate Medicare beneficiaries. A different commenter provided an unpublished study that they believe demonstrates that safety, efficacy, and patient satisfaction for lumbar interbody fusion surgery furnished in the ASC setting are comparable to or better than in the hospital setting for Medicare beneficiaries.

The services that commenters believed should remain off the IPO list in CY 2022 and continue to be paid under the OPPS when furnished in the hospital outpatient setting are included in Table 46.

BILLING CODE 4120–01–P

TABLE 46: SERVICES REQUESTED TO REMAIN OFF OF THE IPO LIST FOR CY 2022

CY 2022 CPT Code	CY 2022 Long Descriptor
01486	Anesthesia for open procedures on bones of lower leg, ankle, and foot; total ankle replacement
01634	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; shoulder disarticulation
21141	Reconstruction midface, lefort i; single piece, segment movement in any direction (for example, for long face syndrome), without bone graft
21188	Reconstruction midface, osteotomies (other than lefort type) and bone grafts (includes obtaining autografts)
21194	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation
21255	Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts)
21343	Open treatment of depressed frontal sinus fracture
21344	Open treatment of complicated (for example, comminuted or involving posterior wall) frontal sinus fracture, via coronal or multiple approaches
21347	Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches
21348	Open treatment of nasomaxillary complex fracture (lefort ii type); with bone grafting (includes obtaining graft)
21366	Open treatment of complicated (for example, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)
21422	Open treatment of palatal or maxillary fracture (lefort i type);
21423	Open treatment of palatal or maxillary fracture (lefort i type); complicated (comminuted or involving cranial nerve foramina), multiple approaches
21436	Open treatment of craniofacial separation (lefort iii type); complicated, multiple surgical approaches, internal fixation, with bone grafting (includes obtaining graft)
21510	Incision, deep, with opening of bone cortex (for example, for osteomyelitis or bone abscess), thorax
21620	Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy
22010	Incision and drainage, open, of deep abscess (subfascial), posterior spine; cervical, thoracic, or cervicothoracic
22015	Incision and drainage, open, of deep abscess (subfascial), posterior spine; lumbar, sacral, or lumbosacral

22110	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; cervical
22112	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; thoracic
22114	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar
22116	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)
22210	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical
22212	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar
22216	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (list separately in addition to primary procedure)
22220	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; cervical
22222	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar
22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)
22318	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; without grafting
22319	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; with grafting
22325	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; lumbar
22326	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; cervical
22532	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (list separately in addition to code for primary procedure)

22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22595	Arthrodesis, posterior technique, atlas-axis (c1-c2)
22600	Arthrodesis, posterior or posterolateral technique, single level; cervical below c2 segment
22610	Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral transverse technique, when performed)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments
22830	Exploration of spinal fusion
22841	Internal spinal fixation by wiring of spinous processes (list separately in addition to code for primary procedure)
22843	Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (list separately in addition to code for primary procedure)
22844	Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (list separately in addition to code for primary procedure)
22846	Anterior instrumentation; 4 to 7 vertebral segments (list separately in addition to code for primary procedure)
22847	Anterior instrumentation; 8 or more vertebral segments (list separately in addition to code for primary procedure)

22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (list separately in addition to code for primary procedure)
22849	Reinsertion of spinal fixation device
22850	Removal of posterior nonsegmental instrumentation (for example, harrington rod)
22852	Removal of posterior segmental instrumentation
22855	Removal of anterior instrumentation
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
23200	Radical resection of tumor; clavicle
23210	Radical resection of tumor; scapula
23220	Radical resection of tumor, proximal humerus
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (for example, total shoulder)
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (for example, total shoulder))
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component
24940	Cineplasty, upper extremity, complete procedure
25900	Amputation, forearm, through radius and ulna;
25905	Amputation, forearm, through radius and ulna; open, circular (guillotine)
25915	Krukenberg procedure
25920	Disarticulation through wrist;
25924	Disarticulation through wrist; re-amputation
25927	Transmetacarpal amputation;
26556	Transfer, free toe joint, with microvascular anastomosis
26992	Incision, bone cortex, pelvis and/or hip joint (for example, osteomyelitis or bone abscess)
27005	Tenotomy, hip flexor(s), open (separate procedure)
27025	Fasciotomy, hip or thigh, any type
27030	Arthrotomy, hip, with drainage (for example, infection)
27036	Capsulectomy or capsulotomy, hip, with or without excision of heterotopic bone, with release of hip flexor muscles (i.e., gluteus medius, gluteus minimus, tensor fascia latae, rectus femoris, sartorius, iliopsoas)
27054	Arthrotomy with synovectomy, hip joint
27122	Acetabuloplasty; resection, femoral head (e.g., girdlestone procedure)
27125	Hemiarthroplasty, hip, partial (for example, femoral stem prosthesis, bipolar arthroplasty)

27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft
27187	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate, femoral neck and proximal femur
27248	Open treatment of greater trochanteric fracture, includes internal fixation, when performed
27457	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); after epiphyseal closure
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component
27495	Prophylactic treatment (nailing, pinning, plating, or wiring) with or without methylmethacrylate, femur
27702	Arthroplasty, ankle; with implant (total ankle)
27703	Arthroplasty, ankle; revision, total ankle
27712	Osteotomy; multiple, with realignment on intramedullary rod (for example, sofield type procedure)
27715	Osteoplasty, tibia and fibula, lengthening or shortening
27724	Repair of nonunion or malunion, tibia; with iliac or other autograft (includes obtaining graft)
27725	Repair of nonunion or malunion, tibia; by synostosis, with fibula, any method
27727	Repair of congenital pseudarthrosis, tibia
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral
35800	Exploration for postoperative hemorrhage, thrombosis or infection; neck
37182	Insertion of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract formation/dilatation, stent placement and all associated imaging guidance and documentation)
37617	Ligation, major artery (e.g., post-traumatic, rupture); abdomen
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury
44300	Placement, enterostomy or cecostomy, tube open (e.g., for feeding or decompression) (separate procedure)
44314	Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)
44345	Revision of colostomy; complicated (reconstruction in-depth) (separate procedure)

44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)
44602	Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture; single perforation
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)
49255	Omentectomy, epiploectomy, resection of omentum (separate procedure)
51840	Anterior vesicourethropexy, or urethropexy (e.g., marshall-marchetti-krantz, burch); simple
56630	Vulvectomy, radical, partial;
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)

BILLING CODE 4120–01–C

Response: We conducted an additional clinical review and reevaluation using the five longstanding criteria for removing services from the IPO list discussed earlier in section IX.A of this final rule with comment period for the services we proposed to return to the IPO list to determine whether any of the procedures should remain off of the list and be paid for under the OPPS when furnished in the HOPD setting. We considered all the evidence that commenters submitted to demonstrate that a procedure was performed on an outpatient basis in a safe and appropriate manner—including but not limited to—operative reports of actual cases, peer-reviewed medical literature, community medical standards and practice, physician comments, outcome data, and post-procedure care data, and our medical advisors thoroughly reviewed all information submitted to determine whether the procedures meet the evaluation criteria we are reinstating.

We also conducted an additional review of 2021 OPPS claims data through September 2021. Our review indicated that hospitals have significantly increased the numbers of services described by CPT codes 22630 (Lumbar spine fusion), 23472 (Reconstruct shoulder joint), and 27702 (Reconstruct ankle joint) furnished in the hospital outpatient setting in the roughly nine months since the services were removed from the IPO list. While at this time we cannot determine from the claims data whether this increase in volume is a result of fundamental changes to clinical practice; the impact of the PHE on inpatient operating room availability; or other reasons, the data do indicate that these services are being furnished frequently in the hospital outpatient setting, and furnished at a substantial number of different outpatient departments. Given the studies submitted and the updated analyses of OPPS claims data, we believe that CPT codes 22630 (Lumbar spine fusion), 23472 (Reconstruct shoulder joint), and 27702 (Reconstruct ankle joint) meet several of the longstanding criteria for removing services from the IPO list: Most outpatient departments are equipped to provide the services to the Medicare population; the simplest procedure described by the codes may be furnished in most outpatient departments; the procedures are being furnished in numerous hospitals on an outpatient basis; and the procedures are related to codes that we have already removed from the IPO list. Therefore, at this time we agree that it is appropriate for CPT codes 22630 (Lumbar spine fusion), 23472 (Reconstruct shoulder joint), and 27702 (Reconstruct ankle joint) and their corresponding anesthesia codes, CPT code 01638 (Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; total shoulder replacement), and CPT 01486 (Anesthesia for open procedures on bones of lower leg, ankle, and foot; total ankle replacement) to remain off the IPO list and payable under the OPPS when furnished in the HOPD setting. We will continue to monitor and evaluate the impact our decision to pay for these services when furnished in the HOPD setting has on beneficiary outcomes, access to care, and hospital payments.

As noted above, we also received comments requesting that approximately 115 other services remain off the IPO list in CY 2022. Based on our evaluation, we do not believe that there is sufficient evidence or data to support that these services can be safely furnished to the typical Medicare beneficiary in the hospital outpatient setting, and to support stakeholder assertions that these procedures meet one of the five longstanding criteria. We note that for many services stakeholders continued to provide conflicting feedback regarding the ability of providers to safely furnish them in the hospital outpatient setting. At this time, we do not believe it would be appropriate to keep these services off of the IPO list and therefore we are reclassifying these codes as inpatient only procedures for CY 2022. We acknowledge the unique circumstances for this CY2022 rulemaking cycle: These approximately 115 services were on the IPO list prior to CY 2021, they were removed from the IPO list for CY 2021 as part of the first phase of the elimination of the IPO list, and are now being added back to the list in CY 2022. It is not our intention to cause any disruptions or barriers to access care for these services, and we will prioritize the review of these services for potential removal from the IPO list in future rulemaking. We emphasize that the assignment of a service to the IPO list does not prohibit the service from being offered in the hospital outpatient setting and the assignment in this final rule should not be considered as a permanent or irrevocable designation (65 FR 18456). Furthermore, we continue to encourage stakeholders to provide supportive evidence to aid in the evaluations of procedures' assignment to the IPO list, and where appropriate the APC assignment and corresponding payment for any codes as well, including but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols for future rulemaking considerations.

4. Topics and Questions Posed for Public Comments

In addition to our proposal to halt the elimination of the IPO list and return services summarily removed from the IPO list in CY 2021 that our clinicians have determined do not meet the criteria for removal from the IPO list, we also sought feedback from stakeholders on whether CMS should maintain the longer-term objective of eliminating the IPO list or if CMS should maintain the IPO list but continue to systematically scale the list back to so that inpatient only designations are consistent with current standards of practice. Specifically, we requested comments on the following:

- Should CMS maintain the longer-term objective of eliminating the IPO list? If so, what is a reasonable timeline for eliminating the list? What method do stakeholders suggest CMS use to approach removing codes from the list?
- Should CMS maintain the IPO list but continue to streamline the list of services included on the list and, if so, suggestions for ways to systematically scale the list back to allow for the removal of codes, or groups of codes, that can safely and effectively be performed on a typical Medicare beneficiary in the hospital outpatient setting so that inpatient only designations are consistent with current standards of practice?
- What effect do commenters believe the elimination or scaling back of the IPO list would have on safety and quality of care for Medicare beneficiaries?
- What effect do commenters believe elimination or the scaling back of the IPO list would have on provider behavior, incentives, or innovation?
- What information or support would be helpful for providers and physicians in their considerations of site of service selections?
- Should CMS' clinical evaluation of the safety of a service in the hospital outpatient setting consider the safety and quality of care for the typical Medicare beneficiary or a smaller subset of Medicare beneficiaries for whom the outpatient provision of a service may have fewer risk factors?
- Are there services that were removed from the IPO list in CY 2021 that stakeholders believe meet the longstanding criteria for removal from the IPO list and should continue to be payable in the hospital outpatient setting in CY 2022? If so, what evidence supports the conclusion that the service meets the longstanding criteria for removal from the IPO list and is safe to perform on the Medicare population in the hospital outpatient setting?

Comment: Numerous commenters responded to CMS' comment solicitation on whether CMS should continue the longer-term objective of eliminating the IPO list or if CMS should maintain the IPO list but continue to systematically scale the list back to ensure that inpatient only designations are consistent with current standards of practice. The overwhelming majority of the commenters, including professional associations, hospital associations, hospitals, and many providers, supported maintaining the IPO list.

We received many of the same types of comments we received in response to our CY 2018 OPPS/ASC proposed rule comment solicitation for removing THA and in subsequent rulemaking. Supporters of maintaining the IPO list also acknowledged the possibility that in the future many—but not all—of the services on the IPO could potentially be safely performed on an outpatient basis. Commenters provided feedback on improvements to the IPO list maintenance process, as well as the criteria, evidence and data that should be required to support removing a procedure from the IPO list. Commenters also suggested alternatives to the IPO list, including different coding mechanisms and alternative approaches to APC assignment for services transitioning off of the IPO list, including changes to the ''CA'' modifier, which identifies a procedure payable only in the inpatient setting when performed emergently on an outpatient who expires prior to admission. Commenters also recommended ways for CMS to monitor patient outcomes and the impact of services migrating from the IPO list to ensure that there are not unintended consequences of removing procedures from the IPO list. Several commenters shared concerns regarding the unintended impact that large-scale changes to the IPO list may have on hospital finances, particularly rural hospitals, safety net hospitals, and SNFs.

Response: We thank the commenters for their detailed feedback on this topic. We will consider all of these comments for future rulemaking.

Comment: Several commenters recommended that CPT codes 19306 (Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes); 32853 (Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass); 33523 ((Coronary artery bypass, using venous graft(s) and arterial graft(s), six or more); and 33935 (Heart-lung transplant with recipient cardiectomy-pneumonectomy), never come off of the IPO list due to their clinical intensity and nature of the services.

Response: We thank commenters for their recommendations.

Comment: Additionally, CMS received comments recommending the removal of two services not originally proposed for removal from the IPO list for CY 2022. The commenters contended that CPT codes 43775 (Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (*i.e.,* sleeve gastrectomy)) and 47550 (Biliary endoscopy, intraoperative (choledochoscopy) (list separately in addition to code for primary procedure)) should be removed from the IPO list because the commenters believed they meet the removal criteria that we are reinstating beginning CY 2022.

Response: We thank commenters for their feedback regarding these services. We note CPT codes 43775 and 47550 were not included in the 298 codes that were removed from the IPO list for CY 2021 and then proposed to be added back to the IPO list in the CY 2022 OPPS/ASC proposed rule. Rather, these codes were added to the IPO list prior to 2021. As discussed above, we received many comments from stakeholders regarding the speed at which the 298 services were removed from the IPO list for CY 2021, and the need for CMS to reinstate a more measured process that includes additional opportunities for public input and transparency when evaluating codes for removal. In light of these comments, we believe it is appropriate to consider the removal of these services from the IPO list in future rulemaking in order to allow further discussion and evaluation. We also continue to encourage stakeholders to provide supportive evidence to aid in the evaluations of these procedures' assignment to the IPO list, including but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols for future rulemaking considerations.

Comment: One commenter, a medical device company, requested a reassignment of the OPPS status indicator for CPT code 0643T (Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach) from ''E1'' (not covered by Medicare) to ''C'' (inpatient only) status due to the complex patient population, the need for intra- and post-

operative monitoring and their experience with clinical trials.

Response: We thank the commenter for bringing this CPT code to our attention. CPT code 0643T became effective on July 1, 2021 and for CY 2022, we proposed to assign the code to OPPS status indicator ''E1'' (Items, codes, and services not covered by any Medicare outpatient benefit category; statutorily excluded; not reasonable and necessary) to indicate that the service was not covered by Medicare. We note that the clinical study associated with CPT code 0643T was approved as a Medicare-approved IDE study [190] with a Category B designation [191] for the device effective November 12, 2020. We agree with commenters that given the invasive nature of the procedures, the clinical intensity of the services provided, and the underlying physical condition of the patient who would require surgery, CPT code 0643T should be classified as an inpatient only procedure.

We refer readers to sections III.D. ''OPPS APC-Specific Policies'' of this final rule with comment period for additional discussion regarding CY 2022 status indicators and APC assignments.

Comment: Other commenters requested we keep services off the IPO list that were not included in the proposed CY 2022 IPO list.

Response: We thank commenters for their recommendations. We do agree that it is appropriate for these services to remain payable in the OPPS for CY2022. We reiterate that assignment in this final rule should not be considered as a permanent or irrevocable designation (65 FR 18456). Table 47 lists the CPT codes that were not included in the proposed CY 2022 IPO list and were affirmed by commenters.

BILLING CODE 4120–01–P

TABLE 47: OTHER SERVICES RECOMMENDED BY COMMENTERS FOR OPPS PAYMENT

CY 2022 CPT Code	CY 2022 Long Descriptor
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle
21346	Open treatment of nasomaxillary complex fracture (lefort ii type); with wiring and/or local fixation
21385	Open treatment of orbital floor blowout fracture; transantral approach (caldwell-luc type operation)
21386	Open treatment of orbital floor blowout fracture; periorbital approach
21387	Open treatment of orbital floor blowout fracture; combined approach
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)
21408	Open treatment of fracture of orbit, except blowout; with bone grafting (includes obtaining graft)
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
27447	Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)
31292	Nasal/sinus endoscopy, surgical, with orbital decompression; medial or inferior wall
31293	Nasal/sinus endoscopy, surgical, with orbital decompression; medial and inferior wall
31294	Nasal/sinus endoscopy, surgical, with optic nerve decompression

[190] *Clinical evaluation of the ACCUCINCH® ventricular restoration system in patients who present with symptomatic heart failure with reduced ejection fraction (hfref): The corcinch-HF study—full text view.* Full Text View—*ClinicalTrials.gov.* (n.d.). Retrieved October 22, 2021, from *https://clinicaltrials.gov/ct2/show/NCT04331769.*

[191] *G150249–NCT04331769.* CMS Approved IDE Studies. (n.d.). Retrieved October 22, 2021, from *https://www.cms.gov/medicarecoverageideapproved-ide-studies/g150249-nct04331769.*

CY 2022 CPT Code	CY 2022 Long Descriptor
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (list separately in addition to code for primary procedure)
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (list separately in addition to code for primary procedure)
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (list separately in addition to code for primary procedure)

C. Summary of Final Policy and Changes to the IPO List for CY 2022

As explained above, for CY 2022, we are finalizing our proposal to halt the elimination of the IPO list; to codify in regulation text in a new § 419.22 our five longstanding criteria for determining whether a service or procedure should be removed from the IPO list; and to pause the elimination of the IPO list and add back to the IPO list the services removed in CY 2021, except CPT code 22630 (Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar); CPT code 23472 (Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (for example, total shoulder))); CPT code 27702 (Arthroplasty, ankle; with implant (total ankle) and their corresponding anesthesia codes: CPT code 01638 (Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; total shoulder replacement), and CPT 01486 (Anesthesia for open procedures on bones of lower leg, ankle, and foot; total ankle replacement). We are also classifying CPT code 0643T (Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach) as an inpatient only procedure. Finally, we are also finalizing our proposal to amend the regulation at § 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a 3-year transition and to codify our five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation in a new § 419.23.

The complete list of codes describing services that are designated as inpatient only services beginning in CY 2022 is also included as Addendum E to this final rule with comment period, which is available via the internet on the CMS website.

TABLE 48: CHANGES TO THE INPATIENT ONLY (IPO) LIST FOR CY 2022

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
00192	Anesthesia for procedures on facial bones or skull; radical surgery (including prognathism)	Add to the IPO list	N/A	C
00474	Anesthesia for partial rib resection; radical procedures (eg, pectus excavatum)	Add to the IPO list	N/A	C
00604	Anesthesia for procedures on cervical spine and cord; procedures with patient in the sitting position	Add to the IPO list	N/A	C
00904	Anesthesia for; radical perineal procedure	Add to the IPO list	N/A	C
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
01140	Anesthesia for interpelviabdominal (hindquarter) amputation	Add to the IPO list	N/A	C
01150	Anesthesia for radical procedures for tumor of pelvis, except hindquarter amputation	Add to the IPO list	N/A	C
01212	Anesthesia for open procedures involving hip joint; hip disarticulation	Add to the IPO list	N/A	C
01232	Anesthesia for open procedures involving upper two-thirds of femur; amputation	Add to the IPO list	N/A	C
01234	Anesthesia for open procedures involving upper two-thirds of femur; radical resection	Add to the IPO list	N/A	C
01274	Anesthesia for procedures involving arteries of upper leg, including bypass graft; femoral artery embolectomy	Add to the IPO list	N/A	C
01404	Anesthesia for open or surgical arthroscopic procedures on knee joint; disarticulation at knee	Add to the IPO list	N/A	C
01486	Anesthesia for open procedures on bones of lower leg, ankle, and foot; total ankle replacement	Remain off the IPO list	N/A	N
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
01634	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; shoulder disarticulation	Add to the IPO list	N/A	C
01636	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; interthoracoscapular (forequarter) amputation	Add to the IPO list	N/A	C
01638	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; total shoulder replacement	Remain off the IPO list	N/A	N

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
01756	Anesthesia for open or surgical arthroscopic procedures of the elbow; radical procedures	Add to the IPO list	N/A	C
0202T	Posterior vertebral joint(s) arthroplasty (for example, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine	Add to the IPO list	N/A	C
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical	Add to the IPO list	N/A	C
0220T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic	Add to the IPO list	N/A	C
0643T	Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach	Add to the IPO list	N/A	C
20661	Application of halo, including removal; cranial	Add to the IPO list	N/A	C
20664	Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (eg, pediatric patients, hydrocephalus, osteogenesis imperfecta)	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
20802	Replantation, arm (includes surgical neck of humerus through elbow joint), complete amputation	Add to the IPO list	N/A	C
20805	Replantation, forearm (includes radius and ulna to radial carpal joint), complete amputation	Add to the IPO list	N/A	C
20808	Replantation, hand (includes hand through metacarpophalangeal joints), complete amputation	Add to the IPO list	N/A	C
20816	Replantation, digit, excluding thumb (includes metacarpophalangeal joint to insertion of flexor sublimis tendon), complete amputation	Add to the IPO list	N/A	C
20824	Replantation, thumb (includes carpometacarpal joint to MP joint), complete amputation	Add to the IPO list	N/A	C
20827	Replantation, thumb (includes distal tip to MP joint), complete amputation	Add to the IPO list	N/A	C
20838	Replantation, foot, complete amputation	Add to the IPO list	N/A	C
20955	Bone graft with microvascular anastomosis; fibula	Add to the IPO list	N/A	C
20956	Bone graft with microvascular anastomosis; iliac crest	Add to the IPO list	N/A	C
20957	Bone graft with microvascular anastomosis; metatarsal	Add to the IPO list	N/A	C
20962	Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal	Add to the IPO list	N/A	C
20969	Free osteocutaneous flap with microvascular anastomosis; other than iliac crest, metatarsal, or great toe	Add to the IPO list	N/A	C
20970	Free osteocutaneous flap with microvascular anastomosis; iliac crest	Add to the IPO list	N/A	C
21045	Excision of malignant tumor of mandible; radical resection	Add to the IPO list	N/A	C
21141	Reconstruction midface, lefort i; single piece, segment movement in any direction (for example, for long face syndrome), without bone graft	Add to the IPO list	N/A	C
21142	Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
21143	Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft	Add to the IPO list	N/A	C
21145	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	Add to the IPO list	N/A	C
21146	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	Add to the IPO list	N/A	C
21147	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	Add to the IPO list	N/A	C
21151	Reconstruction midface, LeFort II; any direction, requiring bone grafts (includes obtaining autografts)	Add to the IPO list	N/A	C
21154	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); without LeFort I	Add to the IPO list	N/A	C
21155	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); with LeFort I	Add to the IPO list	N/A	C
21159	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); without LeFort I	Add to the IPO list	N/A	C
21160	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); with LeFort I	Add to the IPO list	N/A	C
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)	Add to the IPO list	N/A	C
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
21182	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting less than 40 sq cm	Add to the IPO list	N/A	C
21183	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 40 sq cm but less than 80 sq cm	Add to the IPO list	N/A	C
21184	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 80 sq cm	Add to the IPO list	N/A	C
21188	Reconstruction midface, osteotomies (other than lefort type) and bone grafts (includes obtaining autografts)	Add to the IPO list	N/A	C
21194	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)	Add to the IPO list	N/A	C
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	Add to the IPO list	N/A	C
21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (for example, for hemifacial microsomia)	Add to the IPO list	N/A	C
21255	Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts)	Add to the IPO list	N/A	C
21268	Orbital repositioning, periorbital osteotomies, unilateral, with bone	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
	grafts; combined intra- and extracranial approach			
21343	Open treatment of depressed frontal sinus fracture	Add to the IPO list	N/A	C
21344	Open treatment of complicated (for example, comminuted or involving posterior wall) frontal sinus fracture, via coronal or multiple approaches	Add to the IPO list	N/A	C
21347	Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches	Add to the IPO list	N/A	C
21348	Open treatment of nasomaxillary complex fracture (lefort ii type); with bone grafting (includes obtaining graft)	Add to the IPO list	N/A	C
21366	Open treatment of complicated (for example, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)	Add to the IPO list	N/A	C
21422	Open treatment of palatal or maxillary fracture (lefort i type);	Add to the IPO list	N/A	C
21423	Open treatment of palatal or maxillary fracture (lefort i type); complicated (comminuted or involving cranial nerve foramina), multiple approaches	Add to the IPO list	N/A	C
21431	Closed treatment of craniofacial separation (lefort iii type) using interdental wire fixation of denture or splint	Add to the IPO list	N/A	C
21432	Open treatment of craniofacial separation (lefort iii type); with wiring and/or internal fixation	Add to the IPO list	N/A	C
21433	Open treatment of craniofacial separation (lefort iii type); complicated (for example, comminuted or involving cranial nerve foramina), multiple surgical approaches	Add to the IPO list	N/A	C
21435	Open treatment of craniofacial separation (lefort iii type); complicated, utilizing internal and/or external fixation techniques (for	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
	example, head cap, halo device, and/or intermaxillary fixation)			
21436	Open treatment of craniofacial separation (lefort iii type); complicated, multiple surgical approaches, internal fixation, with bone grafting (includes obtaining graft)	Add to the IPO list	N/A	C
21510	Incision, deep, with opening of bone cortex (for example, for osteomyelitis or bone abscess), thorax	Add to the IPO list	N/A	C
21602	Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy	Add to the IPO list	N/A	C
21603	Excision of chest wall tumor involving rib(s), with plastic reconstruction; with mediastinal lymphadenectomy	Add to the IPO list	N/A	C
21615	Excision first and/or cervical rib;	Add to the IPO list	N/A	C
21616	Excision first and/or cervical rib; with sympathectomy	Add to the IPO list	N/A	C
21620	Ostectomy of sternum, partial	Add to the IPO list	N/A	C
21627	Sternal debridement	Add to the IPO list	N/A	C
21630	Radical resection of sternum;	Add to the IPO list	N/A	C
21632	Radical resection of sternum; with mediastinal lymphadenectomy	Add to the IPO list	N/A	C
21705	Division of scalenus anticus; with resection of cervical rib	Add to the IPO list	N/A	C
21740	Reconstructive repair of pectus excavatum or carinatum; open	Add to the IPO list	N/A	C
21750	Closure of median sternotomy separation with or without debridement (separate procedure)	Add to the IPO list	N/A	C
21825	Open treatment of sternum fracture with or without skeletal fixation	Add to the IPO list	N/A	C
22010	Incision and drainage, open, of deep abscess (subfascial), posterior spine; cervical, thoracic, or cervicothoracic	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
22015	Incision and drainage, open, of deep abscess (subfascial), posterior spine; lumbar, sacral, or lumbosacral	Add to the IPO list	N/A	C
22110	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; cervical	Add to the IPO list	N/A	C
22112	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; thoracic	Add to the IPO list	N/A	C
22114	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar	Add to the IPO list	N/A	C
22116	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
22206	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); thoracic	Add to the IPO list	N/A	C
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); lumbar	Add to the IPO list	N/A	C
22208	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); each additional vertebral segment (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
22210	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
22212	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic	Add to the IPO list	N/A	C
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar	Add to the IPO list	N/A	C
22216	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (list separately in addition to primary procedure)	Add to the IPO list	N/A	C
22220	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; cervical	Add to the IPO list	N/A	C
22222	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic	Add to the IPO list	N/A	C
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	Add to the IPO list	N/A	C
22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
22318	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; without grafting	Add to the IPO list	N/A	C
22319	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; with grafting	Add to the IPO list	N/A	C
22325	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; lumbar	Add to the IPO list	N/A	C
22326	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
	fractured vertebra or dislocated segment; cervical			
22327	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; thoracic	Add to the IPO list	N/A	C
22328	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; each additional fractured vertebra or dislocated segment (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
22532	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	Add to the IPO list	N/A	C
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	Add to the IPO list	N/A	C
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-c1-c2 (atlas-axis), with or without excision of odontoid process	Add to the IPO list	N/A	C
22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	Add to the IPO list	N/A	C
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
	(other than for decompression); lumbar			
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, l5-s1 interspace	Add to the IPO list	N/A	C
22590	Arthrodesis, posterior technique, craniocervical (occiput-c2)	Add to the IPO list	N/A	C
22595	Arthrodesis, posterior technique, atlas-axis (c1-c2)	Add to the IPO list	N/A	C
22600	Arthrodesis, posterior or posterolateral technique, single level; cervical below c2 segment	Add to the IPO list	N/A	C
22610	Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral transverse technique, when performed)	Add to the IPO list	N/A	C
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar)	Remain off the IPO list	5116	J1
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments	Add to the IPO list	N/A	C
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments	Add to the IPO list	N/A	C
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments	Add to the IPO list	N/A	C
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments	Add to the IPO list	N/A	C
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments	Add to the IPO list	N/A	C
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments	Add to the IPO list	N/A	C
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments	Add to the IPO list	N/A	C
22830	Exploration of spinal fusion	Add to the IPO list	N/A	C
22841	Internal spinal fixation by wiring of spinous processes (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
22843	Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
22844	Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
22846	Anterior instrumentation; 4 to 7 vertebral segments (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
22847	Anterior instrumentation; 8 or more vertebral segments (list separately in addition to code for primary procedure)	Add to the IPO list	N/A	C
22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (list	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
	separately in addition to code for primary procedure)			
22849	Reinsertion of spinal fixation device	Add to the IPO list	N/A	C
22850	Removal of posterior nonsegmental instrumentation (for example, harrington rod)	Add to the IPO list	N/A	C
22852	Removal of posterior segmental instrumentation	Add to the IPO list	N/A	C
22855	Removal of anterior instrumentation	Add to the IPO list	N/A	C
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar	Add to the IPO list	N/A	C
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	Add to the IPO list	N/A	C
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	Add to the IPO list	N/A	C
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	Add to the IPO list	N/A	C
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	Add to the IPO list	N/A	C
23200	Radical resection of tumor; clavicle	Add to the IPO list	N/A	C
23210	Radical resection of tumor; scapula	Add to the IPO list	N/A	C
23220	Radical resection of tumor, proximal humerus	Add to the IPO list	N/A	C
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (for example, total shoulder)	Add to the IPO list	N/A	C
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (for example, total shoulder))	Remain off the IPO list	5115	J1

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	Add to the IPO list	N/A	C
23900	Interthoracoscapular amputation (forequarter)	Add to the IPO list	N/A	C
23920	Disarticulation of shoulder;	Add to the IPO list	N/A	C
24900	Amputation, arm through humerus; with primary closure	Add to the IPO list	N/A	C
24920	Amputation, arm through humerus; open, circular (guillotine)	Add to the IPO list	N/A	C
24930	Amputation, arm through humerus; re-amputation	Add to the IPO list	N/A	C
24931	Amputation, arm through humerus; with implant	Add to the IPO list	N/A	C
24940	Cineplasty, upper extremity, complete procedure	Add to the IPO list	N/A	C
25900	Amputation, forearm, through radius and ulna;	Add to the IPO list	N/A	C
25905	Amputation, forearm, through radius and ulna; open, circular (guillotine)	Add to the IPO list	N/A	C
25915	Krukenberg procedure	Add to the IPO list	N/A	C
25920	Disarticulation through wrist;	Add to the IPO list	N/A	C
25924	Disarticulation through wrist; re-amputation	Add to the IPO list	N/A	C
25927	Transmetacarpal amputation;	Add to the IPO list	N/A	C
26551	Transfer, toe-to-hand with microvascular anastomosis; great toe wrap-around with bone graft	Add to the IPO list	N/A	C
26553	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, single	Add to the IPO list	N/A	C
26554	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, double	Add to the IPO list	N/A	C
26556	Transfer, free toe joint, with microvascular anastomosis	Add to the IPO list	N/A	C
26992	Incision, bone cortex, pelvis and/or hip joint (for example, osteomyelitis or bone abscess)	Add to the IPO list	N/A	C
27005	Tenotomy, hip flexor(s), open (separate procedure)	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
27025	Fasciotomy, hip or thigh, any type	Add to the IPO list	N/A	C
27030	Arthrotomy, hip, with drainage (for example, infection)	Add to the IPO list	N/A	C
27036	Capsulectomy or capsulotomy, hip, with or without excision of heterotopic bone, with release of hip flexor muscles (ie, gluteus medius, gluteus minimus, tensor fascia latae, rectus femoris, sartorius, iliopsoas)	Add to the IPO list	N/A	C
27054	Arthrotomy with synovectomy, hip joint	Add to the IPO list	N/A	C
27070	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); superficial	Add to the IPO list	N/A	C
27071	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); deep (subfascial or intramuscular)	Add to the IPO list	N/A	C
27075	Radical resection of tumor; wing of ilium, 1 pubic or ischial ramus or symphysis pubis	Add to the IPO list	N/A	C
27076	Radical resection of tumor; ilium, including acetabulum, both pubic rami, or ischium and acetabulum	Add to the IPO list	N/A	C
27077	Radical resection of tumor; innominate bone, total	Add to the IPO list	N/A	C
27078	Radical resection of tumor; ischial tuberosity and greater trochanter of femur	Add to the IPO list	N/A	C
27090	Removal of hip prosthesis; (separate procedure)	Add to the IPO list	N/A	C
27091	Removal of hip prosthesis; complicated, including total hip prosthesis, methylmethacrylate with or without insertion of spacer	Add to the IPO list	N/A	C
27120	Acetabuloplasty; (for example, whitman, colonna, haygroves, or cup type)	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
27122	Acetabuloplasty; resection, femoral head (for example, girdlestone procedure)	Add to the IPO list	N/A	C
27125	Hemiarthroplasty, hip, partial (for example, femoral stem prosthesis, bipolar arthroplasty)	Add to the IPO list	N/A	C
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	Add to the IPO list	N/A	C
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	Add to the IPO list	N/A	C
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	Add to the IPO list	N/A	C
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft	Add to the IPO list	N/A	C
27140	Osteotomy and transfer of greater trochanter of femur (separate procedure)	Add to the IPO list	N/A	C
27146	Osteotomy, iliac, acetabular or innominate bone;	Add to the IPO list	N/A	C
27147	Osteotomy, iliac, acetabular or innominate bone; with open reduction of hip	Add to the IPO list	N/A	C
27151	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy	Add to the IPO list	N/A	C
27156	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy and with open reduction of hip	Add to the IPO list	N/A	C
27158	Osteotomy, pelvis, bilateral (for example, congenital malformation)	Add to the IPO list	N/A	C
27161	Osteotomy, femoral neck (separate procedure)	Add to the IPO list	N/A	C
27165	Osteotomy, intertrochanteric or subtrochanteric including internal or external fixation and/or cast	Add to the IPO list	N/A	C
27170	Bone graft, femoral head, neck, intertrochanteric or subtrochanteric area (includes obtaining bone graft)	Add to the IPO list	N/A	C
27175	Treatment of slipped femoral epiphysis; by traction, without reduction	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
27176	Treatment of slipped femoral epiphysis; by single or multiple pinning, in situ	Add to the IPO list	N/A	C
27177	Open treatment of slipped femoral epiphysis; single or multiple pinning or bone graft (includes obtaining graft)	Add to the IPO list	N/A	C
27178	Open treatment of slipped femoral epiphysis; closed manipulation with single or multiple pinning	Add to the IPO list	N/A	C
27181	Open treatment of slipped femoral epiphysis; osteotomy and internal fixation	Add to the IPO list	N/A	C
27185	Epiphyseal arrest by epiphysiodesis or stapling, greater trochanter of femur	Add to the IPO list	N/A	C
27187	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate, femoral neck and proximal femur	Add to the IPO list	N/A	C
27222	Closed treatment of acetabulum (hip socket) fracture(s); with manipulation, with or without skeletal traction	Add to the IPO list	N/A	C
27226	Open treatment of posterior or anterior acetabular wall fracture, with internal fixation	Add to the IPO list	N/A	C
27227	Open treatment of acetabular fracture(s) involving anterior or posterior (one) column, or a fracture running transversely across the acetabulum, with internal fixation	Add to the IPO list	N/A	C
27228	Open treatment of acetabular fracture(s) involving anterior and posterior (two) columns, includes t-fracture and both column fracture with complete articular detachment, or single column or transverse fracture with associated acetabular wall fracture, with internal fixation	Add to the IPO list	N/A	C
27232	Closed treatment of femoral fracture, proximal end, neck; with manipulation, with or without skeletal traction	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
27236	Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	Add to the IPO list	N/A	C
27240	Closed treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with manipulation, with or without skin or skeletal traction	Add to the IPO list	N/A	C
27244	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with plate/screw type implant, with or without cerclage	Add to the IPO list	N/A	C
27245	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with intramedullary implant, with or without interlocking screws and/or cerclage	Add to the IPO list	N/A	C
27248	Open treatment of greater trochanteric fracture, includes internal fixation, when performed	Add to the IPO list	N/A	C
27253	Open treatment of hip dislocation, traumatic, without internal fixation	Add to the IPO list	N/A	C
27254	Open treatment of hip dislocation, traumatic, with acetabular wall and femoral head fracture, with or without internal or external fixation	Add to the IPO list	N/A	C
27258	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc);	Add to the IPO list	N/A	C
27259	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc); with femoral shaft shortening	Add to the IPO list	N/A	C
27268	Closed treatment of femoral fracture, proximal end, head; with manipulation	Add to the IPO list	N/A	C
27269	Open treatment of femoral fracture, proximal end, head, includes internal fixation, when performed	Add to the IPO list	N/A	C
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft,	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
	including instrumentation, when performed			
27282	Arthrodesis, symphysis pubis (including obtaining graft)	Add to the IPO list	N/A	C
27284	Arthrodesis, hip joint (including obtaining graft);	Add to the IPO list	N/A	C
27286	Arthrodesis, hip joint (including obtaining graft); with subtrochanteric osteotomy	Add to the IPO list	N/A	C
27290	Interpelviabdominal amputation (hindquarter amputation)	Add to the IPO list	N/A	C
27295	Detachment of hip joint	Add to the IPO list	N/A	C
27303	Incision, deep, with opening of bone cortex, femur or knee (for example, osteomyelitis or bone abscess)	Add to the IPO list	N/A	C
27365	Radical resection of tumor, femur or knee	Add to the IPO list	N/A	C
27445	Arthroplasty, knee, hinge prosthesis (for example, walldius type)	Add to the IPO list	N/A	C
27448	Osteotomy, femur, shaft or supracondylar; without fixation	Add to the IPO list	N/A	C
27450	Osteotomy, femur, shaft or supracondylar; with fixation	Add to the IPO list	N/A	C
27454	Osteotomy, multiple, with realignment on intramedullary rod, femoral shaft (for example, sofield type procedure)	Add to the IPO list	N/A	C
27455	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); before epiphyseal closure	Add to the IPO list	N/A	C
27457	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); after epiphyseal closure	Add to the IPO list	N/A	C
27465	Osteoplasty, femur; shortening (excluding 64876)	Add to the IPO list	N/A	C
27466	Osteoplasty, femur; lengthening	Add to the IPO list	N/A	C
27468	Osteoplasty, femur; combined, lengthening and shortening with femoral segment transfer	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
27470	Repair, nonunion or malunion, femur, distal to head and neck; without graft (for example, compression technique)	Add to the IPO list	N/A	C
27472	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	Add to the IPO list	N/A	C
27486	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	Add to the IPO list	N/A	C
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component	Add to the IPO list	N/A	C
27488	Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee	Add to the IPO list	N/A	C
27495	Prophylactic treatment (nailing, pinning, plating, or wiring) with or without methylmethacrylate, femur	Add to the IPO list	N/A	C
27506	Open treatment of femoral shaft fracture, with or without external fixation, with insertion of intramedullary implant, with or without cerclage and/or locking screws	Add to the IPO list	N/A	C
27507	Open treatment of femoral shaft fracture with plate/screws, with or without cerclage	Add to the IPO list	N/A	C
27511	Open treatment of femoral supracondylar or transcondylar fracture without intercondylar extension, includes internal fixation, when performed	Add to the IPO list	N/A	C
27513	Open treatment of femoral supracondylar or transcondylar fracture with intercondylar extension, includes internal fixation, when performed	Add to the IPO list	N/A	C
27514	Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	Add to the IPO list	N/A	C
27519	Open treatment of femoral fracture, distal end, medial or lateral condyle,	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
	includes internal fixation, when performed			
27535	Open treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed	Add to the IPO list	N/A	C
27536	Open treatment of tibial fracture, proximal (plateau); bicondylar, with or without internal fixation	Add to the IPO list	N/A	C
27540	Open treatment of intercondylar spine(s) and/or tuberosity fracture(s) of the knee, includes internal fixation, when performed	Add to the IPO list	N/A	C
27556	Open treatment of knee dislocation, includes internal fixation, when performed; without primary ligamentous repair or augmentation/reconstruction	Add to the IPO list	N/A	C
27557	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	Add to the IPO list	N/A	C
27558	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	Add to the IPO list	N/A	C
27580	Arthrodesis, knee, any technique	Add to the IPO list	N/A	C
27590	Amputation, thigh, through femur, any level;	Add to the IPO list	N/A	C
27591	Amputation, thigh, through femur, any level; immediate fitting technique including first cast	Add to the IPO list	N/A	C
27592	Amputation, thigh, through femur, any level; open, circular (guillotine)	Add to the IPO list	N/A	C
27596	Amputation, thigh, through femur, any level; re-amputation	Add to the IPO list	N/A	C
27598	Disarticulation at knee	Add to the IPO list	N/A	C
27645	Radical resection of tumor; tibia	Add to the IPO list	N/A	C
27646	Radical resection of tumor; fibula	Add to the IPO list	N/A	C
27702	Arthroplasty, ankle; with implant (total ankle)	Remain off the IPO list	5115	J1

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
27703	Arthroplasty, ankle; revision, total ankle	Add to the IPO list	N/A	C
27712	Osteotomy; multiple, with realignment on intramedullary rod (for example, sofield type procedure)	Add to the IPO list	N/A	C
27715	Osteoplasty, tibia and fibula, lengthening or shortening	Add to the IPO list	N/A	C
27724	Repair of nonunion or malunion, tibia; with iliac or other autograft (includes obtaining graft)	Add to the IPO list	N/A	C
27725	Repair of nonunion or malunion, tibia; by synostosis, with fibula, any method	Add to the IPO list	N/A	C
27727	Repair of congenital pseudarthrosis, tibia	Add to the IPO list	N/A	C
27880	Amputation, leg, through tibia and fibula;	Add to the IPO list	N/A	C
27881	Amputation, leg, through tibia and fibula; with immediate fitting technique including application of first cast	Add to the IPO list	N/A	C
27882	Amputation, leg, through tibia and fibula; open, circular (guillotine)	Add to the IPO list	N/A	C
27886	Amputation, leg, through tibia and fibula; re-amputation	Add to the IPO list	N/A	C
27888	Amputation, ankle, through malleoli of tibia and fibula (for example, syme, pirogoff type procedures), with plastic closure and resection of nerves	Add to the IPO list	N/A	C
28800	Amputation, foot; midtarsal (for example, chopart type procedure)	Add to the IPO list	N/A	C
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral	Add to the IPO list	N/A	C
35800	Exploration for postoperative hemorrhage, thrombosis or infection; neck	Add to the IPO list	N/A	C
37182	Insertion of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract formation/dilatation, stent placement and all associated imaging guidance and documentation)	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
37617	Ligation, major artery (e.g., post-traumatic, rupture); abdomen	Add to the IPO list	N/A	C
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic	Add to the IPO list	N/A	C
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury	Add to the IPO list	N/A	C
44300	Placement, enterostomy or cecostomy, tube open (eg, for feeding or decompression) (separate procedure)	Add to the IPO list	N/A	C
44314	Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)	Add to the IPO list	N/A	C
44345	Revision of colostomy; complicated (reconstruction in-depth) (separate procedure)	Add to the IPO list	N/A	C
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)	Add to the IPO list	N/A	C
44602	Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture; single perforation	Add to the IPO list	N/A	C
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)	Add to the IPO list	N/A	C
49255	Omentectomy, epiploectomy, resection of omentum (separate procedure)	Add to the IPO list	N/A	C
51840	Anterior vesicourethropexy, or urethropexy (e.g., marshall-marchetti-krantz, burch); simple	Add to the IPO list	N/A	C
56630	Vulvectomy, radical, partial;	Add to the IPO list	N/A	C
61624	Transcatheter permanent occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)	Add to the IPO list	N/A	C
G0412	Open treatment of iliac spine(s), tuberosity avulsion, or iliac wing fracture(s), unilateral or bilateral for	Add to the IPO list	N/A	C

CY 2022 CPT Code	CY 2022 Long Descriptor	Final Action	CY 2022 OPPS APC	CY 2022 OPPS Status Indicator
	pelvic bone fracture patterns which do not disrupt the pelvic ring includes internal fixation, when performed			
G0414	Open treatment of anterior pelvic bone fracture and/or dislocation for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation when performed (includes pubic symphysis and/or superior/inferior rami)	Add to the IPO list	N/A	C
G0415	Open treatment of posterior pelvic bone fracture and/or dislocation, for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation, when performed (includes ilium, sacroiliac joint and/or sacrum)	Add to the IPO list	N/A	C

BILLING CODE 4120–01–C

X. Nonrecurring Policy Changes

A. Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2022 and Subsequent Years

1. Background on the 2-Midnight Rule

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), we clarified our policy regarding when an inpatient admission is considered reasonable and necessary for purposes of Medicare Part A payment. Under this policy, we established a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation. Conversely, when a beneficiary enters a hospital for a surgical procedure not designated as an inpatient-only (IPO) procedure as described in 42 CFR 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the beneficiary in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A, regardless of the hour that the beneficiary came to the hospital or whether the beneficiary used a bed. With respect to services designated under the OPPS as IPO list procedures, we explained that because of the intrinsic risks, recovery impacts, or complexities associated with such services, these procedures would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay. We also indicated that there might be further ''rare and unusual'' exceptions to the application of the benchmark, which would be detailed in subregulatory guidance.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), we also finalized the 2-Midnight presumption, which is related to the 2-Midnight benchmark but is a separate medical review policy. The 2-Midnight benchmark represents guidance to reviewers to identify when an inpatient admission is generally reasonable and necessary for purposes of Medicare Part A payment, while the 2-Midnight presumption relates to instructions to medical reviewers regarding the selection of claims for medical review. Specifically, under the 2-Midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order are presumed to be appropriate for Medicare Part A payment and are not the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-Midnight presumption.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70538 through 70549), we revisited the previous rare and unusual exceptions policy and finalized a proposal to allow for case-by-case exceptions to the 2-Midnight benchmark, whereby Medicare Part A payment may be made for inpatient admissions where the admitting physician does not expect the patient to require hospital care spanning 2 midnights, if the documentation in the medical record supports the physician's determination that the patient nonetheless requires inpatient hospital care.

In the CY 2016 OPPS/ASC final rule with comment period, we reiterated our position that the 2-Midnight benchmark provides clear guidance on when a hospital inpatient admission is appropriate for Medicare Part A payment, while respecting the role of physician judgment. We stated that the following criteria will be relevant to determining whether an inpatient admission with an expected length of stay of less than 2 midnights is nonetheless appropriate for Medicare Part A payment:

- Complex medical factors such as history and comorbidities;

- The severity of signs and symptoms;
- Current medical needs; and
- The risk of an adverse event.

The exceptions for procedures on the IPO list and for ''rare and unusual'' circumstances designated by CMS as national exceptions were unchanged by the CY 2016 OPPS/ASC final rule with comment period.

As we stated in the CY 2016 OPPS/ASC final rule with comment period, the decision to formally admit a patient to the hospital is subject to medical review. Specifically, for inpatient admissions not related to a surgical procedure specified by Medicare as an IPO procedure under 42 CFR 419.22(n) and for which there is not a national exception, payment of the claim under Medicare Part A is subject to the clinical judgment of the medical reviewer to determine whether the medical record supports a reasonable expectation of the need for hospital care crossing at least 2 midnights or otherwise supports a need for inpatient care. The medical reviewer's clinical judgment involves the synthesis of all submitted medical record information (for example, progress notes, diagnostic findings, medications, nursing notes, and other supporting documentation) to make a medical review determination on whether the clinical requirements in the relevant policy have been met. In addition, Medicare review contractors must abide by CMS' policies in conducting payment determinations, but are permitted to take into account evidence-based guidelines or commercial utilization tools that may aid such a decision. While Medicare review contractors may continue to use commercial screening tools to help evaluate the inpatient admission decision for purposes of payment under Medicare Part A, such tools are not binding on the hospital, CMS, or its review contractors. This type of information also may be appropriately considered by the physician as part of the complex medical judgment that guides their decision to keep a beneficiary in the hospital and formulation of the expected length of stay.

2. Current Policy for Medical Review of Inpatient Hospital Admissions for Procedures Removed From the Inpatient Only List

In the CY 2020 OPPS/ASC final rule with comment period we finalized a policy to exempt procedures that have been removed from the IPO list from certain medical review activities to assess compliance with the 2-Midnight rule within the 2 calendar years following their removal from the IPO list. We stated that these procedures will not be considered by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs) in determining whether a provider exhibits persistent noncompliance with the 2-Midnight rule for purposes of referral to the RAC nor will these procedures be reviewed by RACs for ''patient status.'' We explained that during this 2-year period, BFCC–QIOs will have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule, but claims identified as noncompliant will not be denied with respect to the site-of-service under Medicare Part A.

For CY 2021 we proposed to continue the 2-year exemption from site-of-service claim denials, BFCC–QIO referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. However, we finalized our proposal with modifications in the CY 2021 OPPS/ASC final rule with comment period. Instead of the 2-year exemption, procedures removed from the IPO list after January 1, 2021 were indefinitely exempted from site-of-service claim denials under Medicare Part A, eligibility for BFCC–QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service). We stated that this exemption would last until we have Medicare claims data indicating that the procedure is more commonly performed in the outpatient setting than the inpatient setting. Thus, for the exemption to end for a specific procedure, in a single calendar year we would need to have Medicare claims data indicating that the procedure was performed more than 50 percent of the time in the outpatient setting. We stated that we would revisit in rulemaking whether an exemption for a procedure should be ended or whether we may consider additional metrics in the future that could assist us in determining when the exemption period should end for a procedure. Even during this exemption period, the BFCC–QIOs retain the authority to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule, but claims identified as noncompliant will not be denied with respect to the site-of-service under Medicare Part A. Additionally, we stated that we may still conduct medical review in cases in which we believe there is potential fraud or abuse occurring. We explained that the elimination of the IPO list was a large scale change that created brand new considerations for providers regarding site-of-service determinations. At the time, we believed a change of this significance required us to reevaluate our stance on the exemption period for procedures removed from the IPO list, resulting in our decision to finalize an indefinite exemption period rather than continuing the previous 2 year exemption period.

Finally, in the CY 2021 OPPS/ASC final rule with comment period we amended 42 CFR 412.3 to clarify when a procedure removed from the IPO is exempt from certain medical review activities. We stated that for those services and procedures removed between January 1 and December 31, 2020, this exemption will last for 2 years from the date of such removal. For those services and procedures removed on or after January 1, 2021, this exemption will last until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting.

3. Medical Review of Inpatient Hospital Admissions for Procedures Removed From the Inpatient Only List for CY 2022 and Subsequent Years

As stated earlier in this section, services on the IPO list are not subject to the 2-Midnight rule for purposes of determining whether payment is appropriate under Medicare Part A. However, the 2-Midnight rule is applicable once services have been removed from the IPO list. Outside of the exemption periods discussed above, services that have been removed from the IPO list are subject to initial medical reviews of claims for short-stay inpatient admissions conducted by BFCC–QIOs, and are subject to denial for non-compliance with the 2-midnight rule.

BFCC–QIOs may also refer providers to the RACs for further medical review due to exhibiting persistent noncompliance with Medicare payment policies, including, but not limited to:

- Having high denial rates;
- Consistently failing to adhere to the 2-Midnight rule; or
- Failing to improve their performance after QIO educational intervention.

As stated in section IX. of the CY 2022 OPPS/ASC proposed rule (86 FR 42155 through 42176), CMS proposed to halt the elimination of the IPO list. In accordance with this proposal, we proposed to amend 42 CFR 419.22(n) to remove the reference to the elimination

of the list of services and procedures designated as requiring inpatient care through a 3-year transition. We also proposed to return 298 procedures removed from the IPO list in CY 2021 to the IPO list for CY 2022.

Regardless of the status of the IPO list, we believe that the 2-Midnight benchmark remains an important metric to help guide when Part A payment for inpatient hospital admissions is appropriate. As technology advances and more services may be safely performed in the hospital outpatient setting and paid under the OPPS, it is increasingly important for physicians to exercise their clinical judgment in determining the generally appropriate clinical setting for their patient to receive a procedure, whether that be as an inpatient or on an outpatient basis. Importantly, removal of a service from the IPO list has never meant that a beneficiary cannot receive the service as a hospital inpatient—as always, the physician should use his or her complex medical judgment to determine the appropriate setting on a case by case basis.

As stated previously, our current policy regarding IPO list procedures is that they are appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay. Halting the elimination of the IPO list would mean that this will remain true for all services that are still on the list. As in previous years, any services that are removed from the list in the future will be subject to the 2-Midnight benchmark and 2-Midnight presumption. This means that for services removed from the IPO list, under the 2-Midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after admission will be presumed to be appropriate for Medicare Part A payment and will not be the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-Midnight presumption. Additionally, under the 2-Midnight benchmark, services formerly on the IPO list will be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the medical record supports either the admitting physician's reasonable expectation that the patient will require a stay that crosses at least 2 midnights, or the physician's determination that the patient required inpatient hospital care despite an expectation of a shorter length of stay.

Because we proposed to halt the elimination of the IPO list and add 298 services that were removed back to the IPO list, we believed this proposed change required us to reexamine the applicable exemption period. We noted in the CY 2021 OPPS/ASC final rule with comment period that we may shorten the exemption period for a procedure if necessary. We heard from many commenters last year that the 2-year exemption was appropriate when CMS was removing a smaller volume of procedures from the IPO list. However, commenters believed that the unprecedented volume of procedures becoming subject to the 2-Midnight rule with the phased elimination of the IPO list would necessitate a longer exemption period. While these commenters expressed their support for continuing the 2-year exemption, they further stated that a longer exemption period may be more appropriate. Some commenters suggested that anywhere between 3 to 6 years or indefinitely would be appropriate. Commenters expressed their belief that increasing the length of the exemption would be necessary to allow hospitals and practitioners sufficient time to adjust their billing and clinical systems, as well as processes used to determine the appropriate setting of care. For a full description of the comments received please refer to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86115).

We noted in the CY 2022 OPPS/ASC proposed rule that we believed that the indefinite exemption was appropriate when the agency was eliminating the IPO list and removing an unprecedented volume of procedures from the list in a short period of time. That would have resulted in a large number of procedures becoming subject to the 2-Midnight rule in a 3-year span. However, we explained in the CY 2022 OPPS/ASC proposed rule that should we finalize our CY 2022 proposal to halt the elimination of the IPO list, there would no longer be an unprecedented volume of procedures removed from the IPO list at once, and thus the indefinite exemption may no longer be appropriate. As we explained in the CY 2021 OPPS/ASC final rule with comment period, the indefinite exemption was necessary given the magnitude of the change for providers. We explained in the CY 2022 OPPS/ASC proposed rule that because we were now proposing to move toward a much smaller volume of procedures becoming subject to the 2-Midnight rule at one time, we believed that in the event we finalized the proposed halt in the elimination of the IPO list, an indefinite exemption from medical review activities related to the 2-Midnight rule would no longer be warranted.

We also explained in the CY 2022 OPPS/ASC proposed rule that we continued to believe that, in order to facilitate compliance with our payment policy for inpatient admissions, some exemption from certain medical review activities for services removed from the IPO list under the OPPS is appropriate. Accordingly, we proposed to rescind the indefinite exemption and instead apply a 2-year exemption from two midnight medical review activities for services removed from the IPO list on or after January 1, 2021. As finalized in the CY 2020 OPPS/ASC final rule with comment period, and unchanged by the CY 2021 rulemaking, services removed from the IPO list between January 1 and December 30, 2020, are currently subject to a 2-year exemption. Accordingly, we stated that under our proposal, the same 2-year exemption would apply to all service removed from the IPO list on or after January 1, 2020. As we explained in the CY 2020 OPPS/ASC final rule with comment period, we believe that a 2-year exemption from certain medical review activities for procedures removed from the IPO list would allow sufficient time for providers to become more familiar with how to comply with the 2-Midnight rule and for hospitals and clinicians to become used to the availability of payment under both the hospital inpatient and outpatient setting for procedures removed from the IPO list. As we indicated in the CY 2022 OPPS/ASC proposed rule, if we finalized our proposal to halt the elimination of the IPO list, we believed that this rationale would apply equally to the smaller number of services that may be removed from the list at any one time in the future, and thus that the same 2-year exemption period is appropriate.

We also noted in the CY 2022 OPPS/ASC proposed rule that, as with the previous 2-year exemption period for services removed from the IPO list between January 1 and December 30, 2020, applying a 2-year exemption period to services removed from the IPO list on or after January 1, 2021, would allow providers time to gather information on procedures newly removed from the IPO list to help inform education and guidance for the broader provider community, develop patient selection criteria to identify which patients are, and are not, appropriate candidates for outpatient procedures, and to develop related policy protocols. We also said that we believed that this exemption period would aid in compliance with our

payment policy for inpatient admissions.

It is important to note that whether there is a limited timeframe or an indefinite exemption from the specified medical review activities, providers are still expected to comply with the 2-Midnight rule. It is also important to note that the 2-Midnight rule does not prohibit procedures from being performed or billed on an inpatient basis. Whether a procedure has an exemption or not does not change what site of service is medically necessary or appropriate for an individual beneficiary. Providers are still expected to use their complex medical judgment to determine the appropriate site of service for each patient and to bill in compliance with the 2-Midnight rule. The exemption is not from the 2-Midnight rule but from certain medical review procedures and site-of-service claim denials.

Absent the removal of an unprecedented number of services at once from the IPO list, we explained in the proposed rule that we continue to believe that a 2-year exemption from BFCC–QIO referral to RACs and RAC ''patient status'' review of the setting for procedures removed from the IPO list under the OPPS and performed in the inpatient setting would be an adequate amount of time to allow providers to gain experience with application of the 2-Midnight rule to these procedures and the documentation necessary for Part A payment for those patients for which the admitting physician determines that the procedures should be furnished in an inpatient setting. Furthermore, we explained that it was our belief that the 2-year exemption from referrals to RACs, RAC patient status review, and claims denials would be sufficient to allow providers time to update their billing systems and gain experience with respect to newly removed procedures eligible to be paid under either the IPPS or the OPPS, while avoiding potential adverse site-of-service determinations. We solicited public comments regarding the appropriate period of time for this exemption. Commenters indicated whether and why they believed the 2-year period is appropriate, or whether they believed a longer or shorter exemption period would be more appropriate.

In summary, for CY 2021 and subsequent years, we proposed to return to the 2-year exemption from site-of-service claim denials, BFCC–QIO referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list under the OPPS on January 1, 2021 or later. Under this proposal, services removed beginning on January 1, 2021 would receive the same 2-year exemption from 2-Midnight medical review activities as currently applies to services removed between January 1 and December 30, 2020, and not the indefinite exemption finalized in the CY 2021 OPPS/ASC final rule with comment period. We encouraged BFCC–QIOs to review these cases for medical necessity in order to educate themselves and the provider community on appropriate documentation for Part A payment when the admitting physician determines that it is medically reasonable and necessary to conduct these procedures on an inpatient basis. We noted that we will monitor changes in site-of-service to determine whether changes may be necessary to certain CMS Innovation Center models. While we proposed to halt the elimination of the IPO list, we sought comment on whether a 2-year time period is appropriate, or if a longer or shorter period may be more warranted. We also explained in the CY 2022 OPPS/ASC proposed rule, that if we did not finalize our proposal to halt the elimination of the IPO list we might continue with the indefinite exemptions. Finally, we proposed to amend 42 CFR 412.3 to clarify when a procedure removed from the IPO list is exempt from certain medical review activities. We proposed that for all services and procedures removed after January 1, 2020, this exemption would last for 2 years from the date of such removal. This would include those services and procedures removed on or after January 1, 2021, for which this exemption would also be for 2 years from the date of such removal.

Comment: Many commenters, including organizations representing health insurance plans, physician associations, and specialty medical associations supported an indefinite exemption from site-of-service claim denials under Medicare Part A, eligibility for BFCC–QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for site-of-service for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. Some of these commenters recommended exemption from site of service reviews until the procedure is performed in the outpatient setting more than 50 percent of the time, or until clinical evidence supports the safety of procedures performed in an outpatient setting. Additional commenters believed CMS should defer to the physician's judgment on the appropriate site of care and exempt providers from site-of-service claims denials beyond the proposed 2-year exemption period. Commenters stated 2 years does not provide enough time for adequate evidence and research to be conducted to demonstrate that procedures removed from the IPO list can be performed safely for Medicare beneficiaries in hospital outpatient settings. According to the commenters, a longer or indefinite exemption period would extend additional protection to beneficiaries and hospitals providing care in outpatient settings.

Other commenters recommended extending site of service review to 3 or 4 years to allow for quality and safety analysis.

Response: We thank the commenters for their recommendations. As we explained in the CY 2021 OPPS/ASC final rule with comment period, we believed that the prior 2-year exemption might not be sufficient given the magnitude of the change for providers due to the elimination of the IPO list. We agreed at the time that due to the unprecedented number of services removed from the IPO list as part of the phased elimination of that list, additional time (beyond 2 years) would be more appropriate for hospitals and practitioners to adjust their billing and clinical systems, as well as develop their own internal processes to determine the appropriate setting of care for their patients, and review for quality and safety. We acknowledged that providers may not be experienced with assessing procedures on the IPO list against the 2-Midnight benchmark and that a longer exemption would allow them ample time to update their processes to make appropriate decisions about whether to admit patients for the large numbers of procedures being removed from the IPO list at the time (85 FR 86116). We also heard from commenters that the 2-year exemption was appropriate when CMS was removing a smaller volume of procedures from the IPO list. We agreed then and still believe now that the 2-year exemption was appropriate when CMS was removing a smaller, more targeted population of procedures from the IPO list. Accordingly, because we are finalizing our proposal to halt the elimination of the IPO list and return most of the removed services back to the list, we are finalizing our proposal without modification to resume the 2-year exemption period for procedures removed from the IPO list for services removed from the IPO list on January 1, 2020 or later.

Comment: Some commenters supported a two-year exemption from 2-midnight medical reviews. They

believed a 2-year exemption will provide sufficient time for physicians to become more familiar with appropriate coding, billing, and documentation requirements for procedures removed from the IPO list. Commenters also noted that the 2-year exemption time period would help facilitate the transition of services off the IPO list and allow for the development of patient selection criteria to identify which patients are appropriate candidates for outpatient procedures. One commenter in support of the 2-year exemption time period also stressed the importance of CMS and BFCC–QIOs providing education to providers when services are removed from the IPO list.

Response: We thank the commenters for their support. The BFCC–QIOs will continue to review claims even while procedures are exempt from denial based on site-of-service in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule (85 FR 86119). Additionally, in the future, we may provide additional educational material regarding considerations for the selection of site-of-service for a procedure to support physicians' decision-making. We note that this additional information will be for informational or educational purposes only and will not be intended to prohibit payment of procedures that were previously included on the IPO list in the outpatient setting.

We appreciate the stakeholders' feedback regarding the appropriate period of time for exemptions from site-of-service claim denials under Medicare Part A, eligibility for BFCC–QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for site-of-service for services removed from the IPO list on January 1, 2021, and later. Given our decision to halt the elimination of the IPO list, and the fact that we are accordingly no longer removing an unprecedented number of procedures from the list at one time, we believe that a 2-year exemption time period is adequate to let providers gain experience with the application of the 2-Midnight rule to those procedures that have been newly removed from the IPO list. We also believe that a 2-year exemption from the medical review activities discussed above for procedures removed from the IPO list will be sufficient time for providers and BFCC–QIOs to understand the documentation necessary to support Part A payment for those patients for which the admitting physician determines that the procedures should be furnished in an inpatient setting. Therefore, we are finalizing our proposed policy without modifications. We are also finalizing our proposal to amend § 412.3 of our regulations to clarify when a procedure removed from the IPO list is exempt from certain medical review activities.

B. Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests

Section 122 of Division CC of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116–260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. The reduced coinsurance will be phased in beginning January 1, 2022. Currently, the addition of any procedure beyond a planned colorectal cancer screening test (for which there is no coinsurance), results in the beneficiary having to pay coinsurance.

Section 1861(pp) of the Act defines ''colorectal cancer screening tests'' and, under sections 1861(pp)(1)(B) and (C) of the Act, identifies ''screening flexible sigmoidoscopy'' and ''screening colonoscopy'' as two of the recognized procedures. During the course of either one of these two procedures, removal of tissue or other matter may become necessary for diagnostic purposes. Among other things, section 1861(pp)(1)(D) of the Act authorizes the Secretary to include in the definition, other tests or procedures and modifications to the tests and procedures described under this subsection, with such frequency and payment limits as the Secretary determines appropriate, in consultation with appropriate organizations. Section 1861(s)(2)(R) of the Act includes colorectal cancer screening tests in the definition of the medical and other health services that fall within the scope of Medicare Part B benefits described in section 1832(a)(1) of the Act. Section 1861(ddd)(3) of the Act includes colorectal cancer screening tests within the definition of ''preventive services.'' In addition, section 1833(a)(1)(Y) of the Act provides for payment for a preventive service under the PFS at 100 percent of the lesser of the actual charge or the fee schedule amount for these colorectal cancer screening tests, and under the OPPS at 100 percent of the OPPS payment amount, when the preventive service is recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B. As such, there is no beneficiary coinsurance for recommended colorectal cancer screening tests as defined in section 1861(pp)(1) of the Act.

Under these statutory provisions, we have issued regulations governing payment for colorectal cancer screening tests at § 410.152(l)(5). We pay 100 percent of the Medicare payment amount established under the applicable payment methodology for the setting for providers and suppliers, and beneficiaries are not required to pay Part B coinsurance for colorectal cancer screening tests (except for barium enemas, which are not recommended by the USPSTF with a grade of A or B).

In addition to colorectal cancer screening tests, which typically are furnished to patients in the absence of signs or symptoms of illness or injury, Medicare also covers various diagnostic tests (see § 410.32). In general, diagnostic tests must be ordered by the physician or practitioner who is treating the beneficiary and who uses the results of the diagnostic test in the management of the patient's specific medical condition. Under Part B, Medicare may cover flexible sigmoidoscopies and colonoscopies as diagnostic tests when those tests are reasonable and necessary as specified in section 1862(a)(1)(A) of the Act. When these services are furnished as diagnostic tests rather than as screening tests, patients are responsible for the Part B coinsurance (20 or 25 percent depending upon the setting) associated with these services.

We define colorectal cancer screening tests in our regulation at § 410.37(a)(1) to include ''flexible screening sigmoidoscopies'' and ''screening colonoscopies, including anesthesia furnished in conjunction with the service.'' Under our current regulations, we exclude from the definition of colorectal screening services, colonoscopies and sigmoidoscopies that begin as screening services, but where a polyp or other growth is found and removed as part of the procedure. The exclusion of these services from the definition of colorectal cancer screening services is based upon longstanding provisions of the statute under section 1834(d)(2)(D) of the Act dealing with the detection of lesions or growths during procedures (See CY 1998 PFS final rule at 62 FR 59048, 59082).

Prior to the enactment of section 122 of the CAA, section 1834(d)(2)(D) of the

Act provided that if, during the course of a screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening flexible sigmoidoscopy, but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal. Similarly, prior to the recent legislative change, section 1834(d)(3)(D) of the Act provided that if, during the course of a screening colonoscopy, a lesion or growth is detected that results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal. In these situations, Medicare pays for the flexible sigmoidoscopy and colonoscopy tests as diagnostic tests rather than as screening tests and the 100 percent payment rate for recommended preventive services under section 1833(a)(1)(Y) of the Act, as codified in our regulation at § 410.152(l)(5), has not applied. As such, beneficiaries currently are responsible for the usual coinsurance that applies to the services (20 or 25 percent of the cost of the services depending upon the setting).

Under section 1833(b) of the Act, before making payment under Medicare Part B for expenses incurred by a beneficiary for covered Part B services, beneficiaries must first meet the applicable deductible for the year. Section 4104 of the Affordable Care Act (that is, the Patient Protection and Affordable Care Act (Pub L. 111–148, March 23, 2010), and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, March 30, 2010), collectively referred to as the ''Affordable Care Act'') amended section 1833(b)(1) of the Act to make the deductible inapplicable to expenses incurred for certain preventive services that are recommended with a grade of A or B by the USPSTF, including colorectal cancer screening tests as defined in section 1861(pp) of the Act. Section 4104 of the Affordable Care Act also added a sentence at the end of section 1833(b)(1) of the Act specifying that the exception to the deductible shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test. Although amendments made by the Affordable Care Act addressed the applicability of the deductible in the case of a colorectal cancer screening test that involves biopsy or tissue removal, they did not alter the coinsurance provision in section 1833(a) of the Act for such procedures. Although public commenters encouraged the agency to eliminate the coinsurance in these circumstances, the agency found that statute did not provide for elimination of the coinsurance (75 FR 73170 at 73431).

Beneficiaries have continued to contact us noting their concern that a coinsurance percentage applies (20 or 25 percent depending upon the setting) under circumstances where they expected to receive only a colorectal screening test to which coinsurance does not apply. Instead, these beneficiaries received what Medicare considers to be a diagnostic procedure because, for example, polyps were discovered and removed during the procedure. Similarly, physicians have expressed concern about the reactions of beneficiaries when they are informed that they will be responsible for coinsurance if polyps are discovered and removed during a procedure that they had expected to be a screening procedure to which coinsurance does not apply.

Section 122 of the CAA addresses this coinsurance issue by successively reducing, over a period of years, the percentage amount of coinsurance for which the beneficiary is responsible. Ultimately, for services furnished on or after January 1, 2030, the coinsurance will be zero.

To implement the amendments made by section 122 of the CAA, we proposed in the CY 2022 PFS proposed rule to modify our regulations to reflect the changes to Medicare statute. As amended, the statute effectively provides that, for services furnished on or after January 1, 2022, a flexible sigmoidoscopy or a colonoscopy can be considered a screening flexible sigmoidoscopy or a screening colonoscopy test even if an additional procedure is furnished to remove tissue or other matter during the screening test. Specifically, section 122(a)(3) of the CAA added a sentence to the end of section 1833(a) of the Act to include as colorectal screening tests described in section 1833(a)(1)(Y) of the Act, a colorectal cancer screening test, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test. We note that only flexible screening sigmoidoscopies and screening colonoscopies are recognized currently as colorectal cancer screening tests that might involve removal of tissue or other matter. This new sentence added under section 1833(a) uses the same language that was used to amend the statute at section 1833(b)(1) of the Act to broaden the scope of colorectal cancer screening tests to which a deductible does not apply. Section 122(b)(1) of the CAA then limits application of the 100 percent Medicare payment rate (that is, no beneficiary coinsurance) under section 1833(a)(1)(Y) of the Act for the additional colorectal cancer screening tests (those that are not screening tests ''but for'' the new sentence at the end of section 1833(a) of the Act) by making payment for them subject to a new section 1833(dd) of the Act. Section 1833(dd) of the Act provides for a series of increases in the Medicare payment rate percentage for those services over successive periods of years through CY 2029. Thereafter, section 1833(dd) of the Act has no effect, so payment for all colorectal cancer screening tests would be made at 100 percent under section 1833(a)(1)(Y) of the Act.

To codify the amendments made by section 122 of the CAA in our regulations, we proposed in the CY 2022 PFS proposed rule to make two modifications to current regulations.

At § 410.37, we proposed in the CY 2022 PFS proposed rule to modify our regulation where we define conditions for and limitations on coverage for colorectal cancer screening tests by adding a new paragraph (j). That paragraph would provide that, effective January 1, 2022, when a planned colorectal cancer screening test, that is, screening flexible sigmoidoscopy or colonoscopy screening test, requires a related procedure, including removal of tissue or other matter, furnished in connection with, as a result of, and in the same clinical encounter as the screening test, it is considered to be a colorectal cancer screening test.

At § 410.152(l)(5), we also proposed in the CY 2022 PFS proposed rule to modify our regulation. There we describe payment for colorectal cancer screening tests. Effective January 1, 2022, we proposed in the CY 2022 PFS proposed rule to provide for an increase in the Medicare payment percentage that is phased in over time. As the Medicare payment percentage increases, the beneficiary coinsurance percentage decreases. We proposed to revise § 410.152(l)(5) to provide that Medicare payment in a specified year is equal to a specified percent of the lesser of the

actual charge for the service or the amount determined under the fee schedule that applies to the test. The phased in Medicare payment percentages for colorectal cancer screening services described in the amendments we proposed in the CY 2022 PFS proposed rule to our regulation at § 410.37(j) (and the corresponding reduction in coinsurance) are as follows:

- 80 percent payment for services furnished during CY 2022 (with coinsurance equal to 20 percent);
- 85 percent payment for services furnished during CY 2023 through CY 2026 (with coinsurance equal to 15 percent);
- 90 percent payment for services furnished during CY 2027 through CY 2029 (with coinsurance equal to 10 percent); and
- 100 percent payment for services furnished from CY 2030 onward (with coinsurance equal to zero percent).

Thus, between CYs 2022 and 2030, the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter will be reduced over time from the current 20 or 25 percent to zero percent beginning CY 2030 and will remain at zero percent thereafter. We refer readers to the CY 2022 PFS proposed rule for the discussion of these changes to the regulations at §§ 410.37 and 410.152(l)(5) to implement section 122 of the CAA.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72019 through 72020), we adopted a policy that all surgical services furnished on the same date as a planned screening colonoscopy, planned flexible sigmoidoscopy, or barium enema be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test for purposes of implementing section 4104(c)(2) of the Affordable Care Act. We created the HCPCS modifier ''PT'' for providers to append to the diagnostic procedure code that is reported instead of the screening colonoscopy, screening flexible sigmoidoscopy HCPCS code, or as a result of the barium enema when the screening test becomes a diagnostic service. Where the modifier appears on a claim, the claims processing system does not apply the Part B deductible for all surgical services on the same date as the diagnostic test. We stated that we believed this interpretation was appropriate because we believe that it would be very rare for an unrelated surgery to occur on the same date as one of these scheduled screening tests (75 FR 72019). We also stated that we would reassess the appropriateness of the proposed definition of services that are furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test that becomes diagnostic in the event of a legislative change to this policy (for example, a statutory change that would remove the coinsurance for these related services in addition to the deductible).

As we did for purposes of implementing section 4104(c)(2) of the Affordable Care Act, to implement the amendments made by section 122 of the CAA, in the CY 2022 OPPS/ASC proposed rule we proposed that all surgical services furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy would be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test for purposes of determining the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter. We explained that we believe this interpretation is appropriate because we continue to believe that it is very rare for an unrelated surgery to occur on the same date as a scheduled colorectal cancer screening. We stated that providers must continue to report HCPCS modifier ''PT'' to indicate that a planned colorectal cancer screening service converted to a diagnostic service. We also noted that, if our proposal was finalized, we would examine the claims data, monitor for any increases in surgical services unrelated to the colorectal cancer screening test performed on the same date as the screening test, and consider revising our policy through rulemaking if there is a notable increase.

Comment: Overall, commenters expressed support for our proposal that all surgical services furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy would be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test for purposes of determining the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter.

Response: We thank commenters for their support.

Comment: Several commenters requested that CMS allow providers to waive coinsurance even earlier than 2030 or accelerate the reduction in the coinsurance amounts if they elect to do so without fear of violating any CMS rules. A commenter stated the gradual reduction in coinsurance amounts will lead to patient confusion and administration challenges. Other commenters stated that if providers are not permitted to accelerate the reductions in the coinsurance amounts, hospitals should be able to voluntarily waive the co-insurance prior to January 1, 2030. The commenters believed this process could be similar to CMS allowing hospitals to reduce the beneficiary copayment for APC payable services below 20 percent. In addition, one commenter requested that CMS allow hospitals the option to waive the co-payment amounts as long as the hospitals electing this option consider it a contractual allowance not counted as bad debt.

Response: Through this rulemaking, we are adopting Medicare regulations regarding beneficiary coinsurance that reflect the decreasing beneficiary financial obligations over time as established by statute. Prior to the complete phaseout of Medicare coinsurance amounts for colorectal cancer screening tests in CY 2030, suppliers may waive coinsurance amounts only if they comply with applicable law, including the Federal Anti-Kickback Statute and the civil monetary penalty provision prohibiting inducements to beneficiaries. We also note that the election to offer reduced copayment amounts provided for in section 1833(t)(8)(B) of the Act provides copayments can be reduced to amounts not less than 20 percent of the OPD fee schedule amount. The coinsurance amount for colorectal cancer screening services in CY 2022 is 20 percent and therefore could not be further reduced under this provision.

We received several comments that were outside the scope of the proposals made in the CY 2022 OPPS/ASC proposed rule. These comments included questions about coverage of bowel preparation products, coverage of non-invasive screening tests that require a follow-up colonoscopy, and cost-sharing for new colorectal screening technologies. Although we are not summarizing and responding to these comments in this final rule, we will take them into consideration for possible future healthcare provider education or rulemaking.

After considering public comments, we are finalizing as proposed the proposals made in the CY 2022 OPPS/

ASC proposed rule to implement section 122 of the CAA. Specifically, we are finalizing that all surgical services furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy would be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test for purposes of determining the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter. Providers must continue to report HCPCS modifier ''PT'' to indicate that a planned colorectal cancer screening service converted to a diagnostic service. We will examine the claims data, monitor for any increases in surgical services unrelated to the colorectal cancer screening test performed on the same date as the screening test, and consider revising our policy through rulemaking if there is a notable increase or abuse of this policy.

C. Low Volume Policy for Clinical and Brachytherapy APCs

Historically, we have used our equitable adjustment authority at section 1833(t)(2)(E) of the Act on a case-by-case basis to adjust how we determine the costs for certain low volume services. In the CY 2016 OPPS/ASC final rule with comment period, we acknowledged that for low volume procedures with significant device costs, the median cost would be a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate for low volume procedures (80 FR 70388 through 70389). We explained that the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. Therefore, in the CY 2016 OPPS/ASC final rule with comment period, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act to use the median cost, rather than the geometric mean, to calculate the payment rate for the procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) for CY 2016.

In the CY 2017 OPPS/ASC final rule with comment period, we adopted a payment policy for low-volume device-intensive procedures similar to the policy we applied to the procedure described by CPT code 0308T. Under this policy, we calculate the payment rate for any device-intensive procedure that is assigned to an APC with fewer than 100 single claims for all procedures in the APC using the median cost instead of the geometric mean cost (81 FR 79660 through 79661). We explained that we believed this policy would help mitigate to some extent the significant year-to-year payment rate fluctuations while preserving accurate claims data-based payment rates for these procedures.

In the CY 2019 OPPS/ASC final rule with comment period, we developed a policy for establishing payment rates for low-volume procedures assigned to New Technology APCs (83 FR 58892 through 58893). In that rule, we explained that procedures assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them (83 FR 58892). One of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new procedure so that it can be assigned to an appropriate clinical APC. We stated that some procedures that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. There is a higher probability that payment data for a procedure with fewer than 100 claims per year may not have a normal statistical distribution, which we were concerned could affect the quality of our standard cost methodology for assigning services to clinical APCs. We also noted that services with fewer than 100 claims per year are not generally considered to be significant contributors to the APC ratesetting calculations, and therefore, are not included in the assessment of the 2 times rule. For these low-volume procedures, we were concerned that the methodology we use to estimate the cost of a procedure under the OPPS—calculating the geometric mean for all separately paid claims for a HCPCS procedure code from the most recent available year of claims data—may not generate an accurate estimate of the actual cost of these procedures.

We noted that low utilization of services can lead to wide variation in payment rates from year to year. This volatility in payment rates from year to year can result in even lower utilization and potential barriers to access for these new technologies, which in turn limits our ability to assign the service to an appropriate clinical APC. To mitigate these issues, we believed that it was appropriate to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs. We finalized a policy to calculate payment rates for low-volume procedures with fewer than 100 claims per year that are assigned to a New Technology APC by using up to four years of claims data to calculate the geometric mean, the median, and the arithmetic mean, to include the result of each statistical methodology in annual rulemaking, and to solicit comment on which methodology should be used to establish the payment rate. We explained that once we identify a payment rate for a low-volume service, we would assign the service to the New Technology APC with the cost band that includes its payment rate (83 FR 58893).

While we believe that the policies we have adopted to calculate payment rates for low-volume procedures have mitigated concerns regarding payment rates for new technologies and device-intensive procedures, we also believe that additional items and services may benefit from a policy that applies to clinical APCs with significantly low claims volume available for ratesetting purposes. In particular, we believe that where there are fewer than 100 single claims from the most recent year available for ratesetting for an APC, there is often significant volatility in the payment rate for those APCs that could be addressed with a low-volume adjustment policy similar to our low-volume policies for device-intensive procedures and New Technology APCs. For example, for CY 2022 ratesetting purposes, there are only 42 single claims from CY 2019 available for determining the geometric mean cost for APC 5244 (Level 4 Blood Product Exchange and Related Services) and the payment rate for this APC has fluctuated significantly from year to year. The geometric mean cost of APC 5244 was $30,424.15 in CY 2018 (based on CY 2016 claims), increased by 25.6 percent to $38,220.27 in CY 2019 (based on CY 2017 claims), and decreased by 18.9 percent to $31,015.17 in CY 2021 (based on CY 2019 claims).

Additionally, for CY 2022 ratesetting purposes, there are only 22 single claims from CY 2019 available for determining the geometric mean cost of APC 2632 (Iodine i-125 sodium iodide). The payment rates for this APC have also fluctuated significantly, with a geometric mean cost of $26.63 in CY 2018 (based on CY 2016 claims), which increased by 43.4 percent to $38.20 in CY 2019 (based on CY 2017 claims), and decreased by 31.8 percent to $26.04 in CY 2021 (based on CY 2019 claims).

As we stated in the CY 2022 OPPS/ASC proposed rule (86 FR 42181 through 42185), we believe that APCs with low claims volume available for ratesetting could also benefit from a low-volume adjustment policy similar to the one we currently utilize to set payment rates for device-intensive

procedures and procedures assigned to New Technology APCs. Specifically, we proposed to expand the existing low volume adjustment policy applied to procedures assigned to New Technology APCs and designate clinical APCs and brachytherapy APCs with fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year (for example, the CY 2019 claims year for this CY 2022 OPPS/ASC proposed rule) as low volume APCs. For clinical and brachytherapy APCs designated as Low Volume, the number of claims available for ratesetting would include claims for all procedures assigned to such APC. Whereas, the existing low volume adjustment policy is applied to procedures assigned to New Technology APCs with fewer than 100 single claims. For APCs designated as low volume and for procedures assigned to New Technology APCs, we proposed to determine a low volume APC's cost and a low volume procedure assigned to a New Technology APC's cost, choosing the ''greatest of'' the median, arithmetic mean, or geometric mean.

We proposed that the threshold for the low volume APC designation would be fewer than 100 single claims per year for the APC that can be used for ratesetting purposes, as this is how we have traditionally defined low volume under our existing policies. We have defined low volume as fewer than 100 single claims under our existing policies as there is a higher probability that payment data for a procedure with fewer than 100 claims per year may not have a normal statistical distribution, which we were concerned could affect how we set payment rates for low volume APCs and procedures assigned to New Technology APCs. For items and services assigned to clinical and brachytherapy APCs we proposed to designate as low volume APCs, we proposed to use up to 4 years of claims data to establish an APC payment rate as we currently do for low volume services assigned to New Technology APCs. The availability of multiple years of claims data will allow for more claims to be used for ratesetting purposes and create a more statistically reliable payment rate for these APCs than setting rates for APCs with low claims volume based on one year of data alone. Further, using multiple years of claims data, we proposed to use the greatest of the median, arithmetic mean, or geometric mean cost to approximate the cost of items and services assigned to a low volume APC. In previous years, we have received few to no public comments on which statistical methodology to use and have usually chosen the methodology that yields the highest rate to set the payment rate for procedures assigned to New Technology APCs. Going forward, we proposed to formalize this approach for low volume procedures assigned to New Technology APCs as well as clinical and brachytherapy APCs. We believe using the greatest of these three methodologies provides a simple and consistent approach to determining the cost metric to be used for ratesetting for these APCs and avoids uncertainty where multiple cost metrics could be used to set the APC's cost. Additionally, due to the payment volatility and low volume nature of these procedures, we believe that choosing the methodology that yields the highest rate will ensure that these procedures receive sufficient payment and that payment is not a barrier to access for these procedures.

Given the different nature of policies that affect the partial hospitalization program (PHP), we did not propose to apply this low volume APC policy to APC 5853 Partial Hospitalization for CMHCs or APC 5863 Partial Hospitalization for Hospital-based PHPs. We are also not proposing to apply this low volume APC policy to APC 2698 (Brachytx, stranded, nos) or APC 2699 (Brachytx, non-stranded, nos), as we believe our current methodology for determining payment rates for non-specified brachytherapy sources, as discussed in section II.A.2.a.(2). of the CY 2022 OPPS/ASC proposed rule (86 FR 42028 through 42029), is appropriate. Further, as discussed in section IV.B.5. of the CY 2022 OPPS/ASC proposed rule (86 FR 42116), we proposed to eliminate our low volume Device-Intensive Procedure policy, as HCPCS code 0308T has been the only procedure subject to this policy, and subsume the ratesetting for HCPCS code 0308T within our broader low volume APC proposal.

For information on our proposed low volume APC designations, see Table 36 of the CY 2022 OPPS/ASC proposed rule (86 FR 42184).

Comment: Many commenters supported our proposal. Commenters stated that the policy would provide a more accurate calculation of cost, help mitigate year-to-year payment fluctuations, and create better predictability in Medicare revenue for hospitals providing these low-volume procedures. One commenter recommended that New Technology C-codes with fewer than 100 claims be eligible for such adjustment. Another commenter recommended that the threshold for Brachytherapy APCs be increased to fewer than 500 claims.

Response: We thank the commenters for their support of our proposal. We are not accepting the recommendation to apply our low-volume adjustment to New Technology C-codes with fewer than 100 claims that are not assigned to New Technology APCs. New Technology C-codes are established to describe procedures that utilize emerging technologies that cannot be adequately described by existing CPT/HCPCS codes. We have routinely assigned such procedures to clinical APCs due to resource and clinical similarity of existing technologies described by other CPT/HCPCS codes and we are not convinced that we should utilize a unique ratesetting process for New Technology C-codes with fewer than 100 claims assigned to clinical APCs. We note that we assign new codes to New Technology APCs only if the service cannot be placed in any of the existing clinical APCs based on clinical similarity and resource homogeneity. Further, we believe our policy of addressing payment fluctuations for clinical and brachytherapy APCs due to limited claims data at the APC level rather than the CPT/HCPCS code level would more appropriately address stakeholder concerns and is more consistent with how our low volume policies have previously addressed limited claims data.

Additionally, we are not accepting the recommendation to modify our criteria and apply a low volume adjustment to brachytherapy APCs with fewer than 500 claims that can be used for ratesetting. As discussed previously, under our existing policies, we believe that our definition of low volume as fewer than 100 single claims per year increases the probability that payment data for a procedure may not have a normal statistical distribution. Further, we believe that applying the same per-year limit of fewer than 100 single claims to all brachytherapy APCs, clinical APCs, and procedures assigned to New Technology APCs to determine whether they should qualify as low volume APCs or low volume procedures is the most consistent and equitable approach.

After considering the public comments we received, we are finalizing our proposal without modification to designate clinical and brachytherapy APCs as low volume APCs if the APC has fewer than 100 claims that can be used for ratesetting. We also are finalizing our proposal to designate procedures assigned to New Technology APCs as low volume

procedures if there are fewer than 100 claims for the procedure that can be used for ratesetting for the year. We are also finalizing our low volume APC payment adjustment to determine the APC cost (or procedure cost in the case of a low volume procedure assigned to a New Technology APC) as the greater of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data. For a discussion of the low volume adjustment as it applies to certain procedures assigned to New Technology APCs, see section III.C. of this final rule with comment period.

In the CY 2022 OPPS/ASC proposed rule (86 FR 42181 through 42185), we proposed to designate three clinical APCs and five brachytherapy APCs as low volume APCs. After reviewing updated CY 2019 claims data available for this final rule, APC 5881 (Ancillary Outpatient Services When Patient Dies) had 99 single claims available for CY 2022 ratesetting purposes. Therefore, with the addition of APC 5881, we are finalizing our proposal, with modification, to designate four clinical APCs and five brachytherapy APCs as low volume APCs under the OPPS. The four clinical APCs and five brachytherapy APCs meet our criteria of having fewer than 100 single claims in the claims year (CY 2019 for the CY 2022 OPPS/ASC final rule with comment period) and therefore, we are finalizing our proposal, with modification, to designate these APCs as low volume APCs. Table 49 illustrates the APC geometric mean cost without the low volume APC designation, the median, arithmetic mean, and geometric mean cost using up to four years of claims data, as well as the statistical methodology we are finalizing to use as the APC's cost for ratesetting purposes for CY 2022. As discussed in section X.E of this final rule with comment period, given our concerns with CY 2020 claims data as a result of the PHE, the 4 years of claims data are based on CY 2016 claims through CY 2019 claims.

BILLING CODE 4120–01–P

TABLE 49: COST STATISTICS FOR LOW VOLUME APCS UNDER C-APCS (OPPS) RATESETTING METHODOLOGY FOR CY 2022

APC	APC Description	Geometric Mean Cost without Low Volume APC Designation	Final Median Cost	Final Arithmetic Mean Cost	Final Geometric Mean Cost	Final CY 2022 APC Cost
2632	Iodine I-125 sodium iodide	$26.04	$30.24	$38.52	$34.16	$38.52
2635	Brachytx, non-str, HA, P-103	$44.37	$34.04	$43.53	$36.72	$43.53
2636	Brachy linear, non-str, P-103	$30.59	$24.78	$50.16	$36.43	$50.16
2645	Brachytx, non-str, Gold-198	$280.90	$61.85	$588.31	$131.86	$588.31
2647	Brachytx, NS, Non-HDRIr-192	$275.13	$145.36	$196.38	$94.24	$196.38
5244	Level 4 Blood Product Exchange and Related Services	$30,715.18	$34,182.25	$39,143.97	$34,076.34	$39,143.97
5494	Level 4 Intraocular Procedures	$14,661.77	$16,272.20	$14,980.87	$11,514.65	$16,272.20
5495	Level 5 Intraocular Procedures	$17,414.85	$17,326.04	$23,057.14	$14,446.26	$23,057.14
5881	Ancillary Outpatient Services When Patient Dies	$8,452.56	$6,980.65	$11,798.18	$7,161.05	$11,798.18

Additionally, for this final rule, based on the number of CY 2019 available claims from the standard ratesetting methodology used for ASC ratesetting purposes in this final rule, for CY 2022, under the ASC payment system, we are also finalizing our proposal to designate the APCs in Table 50 as low volume APCs that meet our criteria of having fewer than 100 single claims in the claims year (CY 2019 for the CY 2022 OPPS/ASC proposed rule) and are subject to our new low volume APC payment adjustment under the ASC payment system. Specifically, we are designating five brachytherapy APCs and four clinical APCs as low volume APCs for CY 2022. These are the same brachytherapy APCs we are finalizing as low volume APCs under the OPPS. We are also designating APC 5244, APC 5494, and APC 5495, which are finalizing as low volume under the OPPS, as low volume under the ASC payment system. Additionally, APC 5493—Level 3 Intraocular Procedures meets our criteria to be designated a low volume APC under the ASC payment system for CY 2022. The payment rates for these APCs are established at the highest amount among the geometric mean, median, or arithmetic mean, calculated using up to four years of data, which, in the case of these APCs, are claims data from 2016 through 2019, based on the standard ratesetting methodology. However, as discussed in section XIII.D.1.d of this final rule with comment period, we are finalizing our proposal to limit the ASC payment rate for procedures assigned to low volume APCs at an amount no greater than the procedure's OPPS payment rate.

TABLE 50: COST STATISTICS FOR LOW VOLUME APCS UNDER STANDARD (ASC) RATESETTING METHODOLOGY FOR CY 2022

APC	APC Description	Geometric Mean Cost without Low Volume APC Designation	Final Median Cost	Final Arithmetic Mean Cost	Final Geometric Mean Cost	Final CY 2022 APC Cost
2632	Iodine I-125 sodium iodide	$26.04	$30.24	$38.52	$34.16	$38.52
2635	Brachytx, non-str, HA, P-103	$44.37	$34.04	$43.53	$36.72	$43.53
2636	Brachy linear, non-str, P-103	$30.59	$24.78	$50.16	$36.43	$50.16
2645	Brachytx, non-str, Gold-198	$280.90	$61.85	$588.31	$131.86	$588.31
2647	Brachytx, NS, Non-HDRIr-192	$275.13	$145.36	$196.38	$94.24	$196.38
5244	Level 4 Blood Product Exchange and Related Services	$28,768.44	$34,012.03	$30,048.41	$12,696.84	$34,012.03
5493	Level 3 Intraocular Procedures	$14,361.84	$11,263.39	$11,057.23	$10,306.97	$11,263.39
5494	Level 4 Intraocular Procedures	$3,085.67	$2,983.13	$3,345.12	$2,943.08	$3,345.12
5495	Level 5 Intraocular Procedures	$17,414.85	$17, 326.04	$25,372.70	$15,453.58	$25,372.70

BILLING CODE 4120–01–C

D. Comment Solicitation on Temporary Policies To Address the COVID–19 PHE

In response to the COVID–19 pandemic, CMS issued waivers and undertook emergency rulemaking to implement a number of temporary policies to address the pandemic, including policies to prevent spread of the infection and support diagnosis of COVID–19. Many of these flexibilities were available because certain statutory or regulatory provisions were waived. These waivers will expire at the conclusion of the PHE. In the CY 2022 OPPS/ASC proposed rule (86 FR 42185) we sought comment on the extent to which stakeholders utilized the flexibilities available under these waivers, as well as whether stakeholders believe certain of these temporary policies should be made permanent to the extent possible within our existing authority. Specifically, we sought comment on stakeholders' experience with hospital staff furnishing services remotely to beneficiaries in their homes through use of communications technology; providers furnishing services in which the direct supervision

for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services requirement was met by the supervising practitioner being available through audio/video real-time communications technology; and the need for specific coding and payment to remain available under the OPPS for specimen collection for COVID–19.

1. Mental Health Services Furnished Remotely by Hospital Staff To Beneficiaries in Their Homes

Under the Physician Fee Schedule (PFS), Medicare makes payment to professionals and other suppliers for physicians' services, including certain diagnostic tests and preventive services. Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of Medicare telehealth services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunications technology. When furnished as Medicare telehealth services under section 1834(m) of the Act, many of these services are still reported using codes that describe ''face-to-face'' services even though they are furnished using audio/video, real-time communications technology instead of in-person (82 FR 53006). Section 1834(m) of the Act specifies the types of health care professionals that can furnish and be paid by Medicare for telehealth services (referred to as distant site practitioners) and the types and locations of settings where a beneficiary can be located when receiving telehealth services (referred to as originating sites). In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare telehealth services list in accordance with section 1834(m)(4)(F)(ii) of the Act (42 CFR 410.78(f)). This process provides the public with an ongoing opportunity to submit requests for adding services, which we consider and review through the annual PFS rulemaking process. The regulation at § 410.78(a)(3) also defines the requirements for the interactive telecommunications systems that may be used to furnish Medicare telehealth services.

Due to the circumstances of the COVID–19 pandemic, particularly the need to maintain physical distance to avoid exposure to the virus, we anticipated that health care practitioners would develop new approaches to providing care using various forms of technology when they are not physically present with the patient. We have established several flexibilities to accommodate these changes in the delivery of care. For Medicare telehealth services, using waiver authority under section 1135(b)(8) of the Act in response to the PHE for the COVID–19 pandemic, we have removed the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act, as well as the restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services, for the duration of the PHE for the COVID–19 pandemic. We also used waiver authority to allow certain telehealth services to be furnished via audio-only communication technology during the PHE.

According to MedPAC's report, *Telehealth in Medicare after the Coronavirus Public Health Emergency,*[192] there were 8.4 million telehealth services paid under the PFS in April 2020, compared with 102,000 in February 2020. MedPAC also reported that during focus groups held in the summer of 2020, clinicians and beneficiaries supported continued access to telehealth visits with some combination of in-person visits. They cited benefits of telehealth, including improved access to care for those with physical impairments, increased convenience from not traveling to an office, and increased access to specialists outside of a local area. In their annual beneficiary survey, over 90 percent of respondents who had a telehealth visit reported being ''somewhat'' or ''very satisfied'' with their video or audio visit, and nearly two-thirds reported being ''very satisfied.''

Division CC, section 123 of the CAA modified the circumstances under which Medicare makes payment for mental health services furnished via telehealth technology under the PFS following the PHE. Specifically, this legislation removed the geographic originating site restrictions and added the home of the individual as a permissible originating site for Medicare telehealth services when furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder.[193] This change correlates with a growing acceptance of the use of technology in the provision of mental health care. According to the Commonwealth Fund,[194] the provision of mental and behavioral health services via communications technology, in particular, has a robust evidence base and numerous studies have demonstrated its effectiveness across a range of modalities and mental health diagnoses (for example, depression, substance use disorders). Clinicians furnishing tele-psychiatry services at Massachusetts General Hospital Department of Psychiatry during the PHE observed several advantages of the virtual format for furnishing psychiatric services, noting that patients with psychiatric pathologies that interfere with their ability to leave home (for example, immobilizing depression, anxiety, agoraphobia, and/or time-consuming obsessive-compulsive rituals) were able to access care more consistently since eliminating the need to travel to a psychiatry clinic can increase privacy and therefore decrease stigma-related barriers to treatment, potentially bringing care to many more patients in need, as well as enhanced ease of scheduling, decreased rate of no-shows, increased understanding of family and home dynamics, and protection for patients and practitioners with underlying health conditions.[195]

These findings are consistent with our analysis of Medicare claims data that indicate that interactive communications technology for mental health care is likely to continue to be in broad use beyond the circumstances of the pandemic. According to our analysis of Medicare Part B claims data for services furnished via Medicare telehealth during the PHE, use of telehealth for many professional services spiked in utilization around April 2020 and diminished over time. In contrast, Medicare claims data suggest that for mental health services added to the Medicare Telehealth list both permanently and temporarily, subsequent to April 2020, the trend is toward maintaining a steady state of usage over time. Given this information, broad acceptance in the public and medical community, and the relatively stable Medicare utilization of mental health services during the COVID–19 pandemic, we believe use of interactive communication technology in furnishing mental health care is becoming an established part of medical practice, very likely to persist after the COVID–19 pandemic, and available

[192] *http://medpac.gov/docs/default-source/reports/mar21_medpac_report_ch14_sec.pdf?sfvrsn=0.*

[193] There is a longstanding statutory payment exclusion that prohibits Medicare payment for services that are not furnished within the United States (see section 1862(a)(4) of the Act). This payment exclusion was not changed by the CAA.

[194] *https://www.commonwealthfund.org/blog/2020/using-telehealth-meet-mental-health-needs-during-covid-19-crisis.*

[195] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7347331/.*

across the country under the Medicare statute for the range of professionals furnishing mental health care and paid under the PFS.

In many cases, hospitals provide hospital outpatient mental health services (including behavioral health), education, and training services that are furnished by hospital-employed counselors or other licensed professionals. Examples of these services include psychoanalysis, psychotherapy, diabetes self-management training, and medical nutrition therapy. With few exceptions, the Medicare statute does not have a benefit category that would allow these types of professionals (for example, mental health counselors and registered nurses) to bill Medicare directly for their services. These services can, in many cases, be billed by providers such as hospitals under the OPPS or by physicians and other practitioners as services incident to their professional services under the PFS. We also note that while partial hospitalization services are paid under the OPPS, section 1861(ff)(3)(A) of the Act explicitly prohibits partial hospitalization services from being furnished in an individual's home or residential setting.

As we explained in the interim final rule with comment period published on May 8, 2020 in the **Federal Register** titled ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (the May 8th COVID–19 IFC) (85 FR 27550, 27563), outpatient mental health services, education, and training services require communication and interaction. We stated that facility staff can effectively furnish these services using telecommunication technology and, unlike many hospital services, the clinical staff and patient are not required to be in the same location to furnish them. We further explained that blanket waivers in effect during the COVID–19 PHE allow the hospital to consider the beneficiary's home, and any other temporary expansion location operated by the hospital during the COVID–19 PHE, to be a provider-based department (PBD) of the hospital, so long as the hospital can ensure the locations meet all of the conditions of participation, to the extent not waived. In light of the need for infection control and a desire for continuity of behavioral health care and treatment services, we recognized the ability of the hospital's clinical staff to continue to deliver these services even when they are not physically located in the hospital. Therefore, in the May 8th COVID–19 IFC (85 FR 27564), we made clear that when a hospital's clinical staff are furnishing hospital outpatient mental health services, education, and training services to a patient in the hospital (which can include the patient's home so long as it is provider-based to the hospital), and the patient is registered as an outpatient of the hospital, we will consider the requirements of the regulations at § 410.27(a)(1) to be met. We reminded readers that the physician supervision level for the vast majority of hospital outpatient therapeutic services is currently general supervision under § 410.27. This means a service must be furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the service.

In the May 8th COVID–19 IFC, we emphasized that all services furnished by the hospital still require an order by a physician or qualified NPP and must be supervised by a physician or other NPP appropriate for supervising the service given their hospital admitting privileges, state licensing, and scope of practice, consistent with the requirements in § 410.27 (85 FR 27563). We noted that hospitals may bill for these services as if they were furnished in the hospital and consistent with any specific requirements for billing Medicare in general, including any relevant modifications in effect during the COVID–19 PHE. We also noted that when these services are provided by clinical staff of the physician or other practitioner and furnished incident to their professional services, and are not provided by staff of the hospital, the hospital would not bill for the services. We stated that in those circumstances, the physician or other practitioner should bill for such services incident to their own services and would be paid under the PFS.

Given that the widespread use of communications technology to furnish services during the PHE has illustrated acceptance within the medical community and among Medicare beneficiaries of the possibility of furnishing and receiving care through the use of that technology, we stated that we were interested in information on the role of hospital staff in providing care to beneficiaries remotely in their homes. During the PHE, hospital staff have had the flexibility to provide these kinds of services to beneficiaries in their homes through communications technology; however, this flexibility is tied to waivers and other temporary policies that expire at the end of the PHE. In instances where a beneficiary may be receiving mental health services from a hospital clinical staff member who cannot bill Medicare independently for their professional service, the beneficiary would then need to physically travel to the hospital to continue receiving the services post-PHE. We stated that we were concerned that this could have a negative impact on access to care in areas where beneficiaries may only be able to access mental health services provided by hospital staff and, during the PHE, have become accustomed to receiving these services in their homes. We also noted that the ability to receive mental health services in their homes may help expand access to care for beneficiaries who prefer additional privacy for the treatment of their condition.

We stated that we were concerned that, during the PHE, practice patterns may have shifted to support expanded virtual services. During the PHE, we have not required any claims-based modifier identifying specifically when a service is furnished by clinical staff of the hospital to a beneficiary in their home through communications technology, and therefore we are not able to gauge the magnitude of these practice pattern shifts. Therefore, we sought comment on the extent to which hospitals have been billing for mental health services provided to beneficiaries in their homes through communications technology during the PHE, and whether they would anticipate continuing demand for this model of care following the conclusion of the PHE. As described in preceding paragraphs, billing for Medicare telehealth services has increased dramatically during the PHE, particularly for mental health services. We sought comment on whether hospitals have experienced a similar increase during the PHE in utilization of mental health services provided by hospital staff to beneficiaries in their homes through communications technology. We also sought comment on whether there are changes commenters believe CMS should make to account for shifting patterns of practice that rely on communication technology to provide mental health services to beneficiaries in their homes.

Comment: Commenters expressed support for continuing OPPS payment for mental health services furnished to beneficiaries in their homes by clinical staff of the hospital through the use of communication technology as a permanent policy post-PHE, stating that the expansion of virtual care broadly during the PHE has been instrumental in maintaining and expanding access to mental health services during the PHE

while keeping beneficiaries in their homes and reducing exposure to COVID. A few commenters requested that CMS continue to allow for the beneficiary's home to be reclassified as a PBD post-PHE, while other commenters stated that CMS should ensure that facility-based providers are adequately reimbursed for their services when furnished remotely. A few commenters encouraged CMS to ensure that there are relevant quality and safety measures for services furnished by hospital staff through communication technology.

Additionally, several commenters expressed support for the flexibilities allowing PHP services to be furnished to beneficiaries in their homes via telecommunication technology during the COVID–19 PHE, and encouraged CMS to maintain these flexibilities beyond the PHE or consider making these temporary policies permanent. Commenters expressed that these flexibilities, especially those allowing the use of audio-only telecommunication technology, increase access to vital mental health services amidst a persistent shortage of health care professionals and allow much greater and timelier access to mental health services, especially in rural areas and for vulnerable populations, while also helping drive reductions in the rates at which patients missed appointments. Commenters also shared research and analysis supporting the effectiveness of providing PHP services using telecommunication technology. One academic health center discussed outcomes analysis it conducted of its PHP services and noted that its analysis did not show a decrement in clinical care for patients who received only virtual PHP services. A national association of behavioral healthcare systems shared research showing that the main differences between patients who participated in PHPs via telecommunication technology and those who attended in-person was that those who participated via telecommunication technology had greater lengths of stay and were more likely to stay in treatment until completed.[196]

Response: We thank commenters for their support. We will consider these comments for future rulemaking and, in addition, will continue to explore how hospital payment for virtual services could support access to care in underserved and/or rural areas.

[196] *https://www.psychiatrist.com/jcp/covid-19/telehealth-treatment-patients-intensive-acute-care-psychiatric-setting-during-covid-19/.*

2. Direct Supervision by Interactive Communications Technology

In the interim final rule with comment period titled ''Policy and Regulatory Provisions in Response to the COVID–19 Public Health Emergency'' published on April 6, 2020 (the April 6th COVID–19 IFC) (85 FR 19230, 19246, 19286), we changed the regulation at 42 CFR 410.27(a)(1)(iv)(D) to provide that, during a Public Health Emergency as defined in § 400.200, the presence of the physician for purposes of the direct supervision requirement for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or practitioner. Specifically, the required direct physician supervision can be provided through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising practitioner. We further amended § 410.27(a)(1)(iv)(D) in the CY 2021 OPPS/ASC final rule with comment period to provide that this flexibility continues until the end of the PHE as defined in § 400.200 or December 31, 2021, whichever is later (85 FR 86113). We noted that the public comments we received, along with feedback we have received since the implementation of the policy in the April 6th COVID–19 IFC allowing for direct supervision through virtual presence (85 FR 19246) have convinced us that we need more information on the issues involved with direct supervision through virtual presence before implementing this policy permanently. We acknowledged that the additional time between the issuance of the CY 2021 OPPS/ASC final rule with comment period and the issuance of the CY 2022 OPPS/ASC proposed rule may have allowed providers to collect more information that could inform CMS' decision making and therefore sought additional comment on whether this policy should be adopted on a permanent basis. While we did not propose to maintain this flexibility after the later of the end of the PHE or December 31, 2021, we did seek comment on whether and to what extent hospitals have relied upon this flexibility during the PHE and whether providers expect this flexibility would be beneficial outside of the PHE. We sought comment on whether we should continue to allow direct supervision for these services to include presence of the supervising practitioner via two-way, audio/video communication technology permanently, or for some period of time after the conclusion of the PHE or beyond December 31, 2021, to facilitate a gradual sunset of the policy. We also sought comment on whether there are safety and/or quality of care concerns regarding adopting this policy beyond the PHE and what policies CMS could adopt to address those concerns if the policy were extended post-PHE. Finally, if this policy were made permanent, we sought comment on whether a service-level modifier should be required to identify when the requirements for direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services were met using audio/video real-time communications technology.

Comment: Commenters supported the adoption of the definition of direct supervision for cardiac rehabilitation and pulmonary rehabilitation, and intensive cardiac rehabilitation services to include presence of the supervising practitioner via two-way, audio/video communication technology on a permanent basis, or, if CMS did not wish to adopt this policy permanently, commenters encouraged CMS to maintain it for a period of time following the conclusion of the PHE, such as until the end of 2022. Most commenters supported development of a service-level modifier, stating that this requirement will allow CMS to track and collect data, although a few commenters stated that requiring a service-level modifier would be unnecessary and create additional burden on providers.

Response: We appreciate commenters' input on this policy and will consider these comments for future rulemaking.

3. Payment for COVID–19 Specimen Collection in Hospital Outpatient Departments

Also in the May 8th COVID–19 IFC, we created a new E/M code to support COVID–19 testing during the PHE: HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars–cov–2) (coronavirus disease [covid–19]), any specimen source) (85 FR 27604). In our review of available HCPCS and CPT codes for the May 8th COVID–19 IFC, we did not identify a code that explicitly described the exact services of symptom assessment and specimen collection that HOPDs were undertaking to facilitate widespread testing for COVID–19. As stated in the May 8th COVID–19 IFC, we believed that HCPCS code C9803 was necessary to meet the resource requirements for HOPDs to provide

extensive testing for the duration of the COVID–19 PHE. This code was created only to meet the need of the COVID–19 PHE and we stated that we expected to retire this code at the conclusion of the COVID–19 PHE (85 FR 27605).

We assigned HCPCS code C9803 to APC 5731—Level 1 Minor Procedures effective March 1, 2020 for the duration of the COVID–19 PHE in accordance with section 1833(t)(2)(B) of the Act, which requires services classified in an APC to be comparable clinically and in terms of resource use. APC 5731—Level 1 Minor Procedures contains services similar to HCPCS code C9803 and has a payment rate of $24.67 for CY 2021. HCPCS code C9803 was also assigned a status indicator of ''Q1.'' The Q1 status indicator indicates that the OPPS will package services billed under HCPCS code C9803 when billed with a separately payable primary service in the same encounter. When HCPCS code C9803 is billed without another separately payable primary service, we will make separate payment for the service under the OPPS. The OPPS also makes separate payment for HCPCS code C9803 when it is billed with a clinical diagnostic laboratory test with a status indicator of ''A'' in OPPS Addendum B.

In the CY 2022 OPPS/ASC proposed rule we solicited public comments on whether we should keep HCPCS code C9803 active beyond the conclusion of the COVID–19 PHE and whether we should extend or make permanent the OPPS payment associated with specimen collection for COVID–19 tests after the COVID–19 PHE ends, including why commenters believe it would be necessary to continue to provide OPPS payment for this service, as well as how long commenters believe payment should be extended for this code.

Comment: Commenters expressed appreciation for CMS' response to the pandemic, including the creation of HCPCS code C9803. One commenter noted that this code has had a positive impact on the delivery of care during the COVID–19 PHE. We received several comments in support of maintaining OPPS payment for HCPCS code C9803 beyond the conclusion of the COVID–19 PHE, with many commenters in support of making payment for this code permanent. Commenters cited concerns regarding the continuation of COVID–19 cases after the conclusion of the COVID–19 PHE and stressed the importance of continued testing in order to track and control COVID–19 cases. Multiple commenters also requested that CMS continue to pay for HCPCS code C9803 due to concerns regarding the unknown future role COVID–19 will play in our lives and potential increases in cases and new mutations of the virus. One commenter also requested that CMS continue payment for HCPCS code C9803 and reevaluate retiring this code when claims volume becomes low.

One commenter also requested that if CMS were to retire HCPCS code C9803, that we provide significant notice and resources to healthcare providers to prevent disruptions in the delivery of care.

Response: We appreciate the comments regarding payment for COVID–19 specimen collection in hospital-based outpatient departments (HOPDs). We plan to take this feedback into consideration for possible future rulemaking.

E. Use of CY 2019 Claims Data for CY 2022 OPPS and ASC Payment System Ratesetting Due to the PHE

As described in section I.A. of the CY 2022 OPPS/ASC proposed rule (86 FR 42020), section 1833(t) of the Act requires the Secretary to annually review and update the payment rates for services payable under the Hospital OPPS. Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review not less often than annually and to revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) of the Act to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

In updating the OPPS payment rates and system for each rulemaking cycle we primarily use two sources of information: The outpatient Medicare claims data and HCRIS cost report data. The claims data source is the Outpatient Standard Analytic File, which includes final action Medicare outpatient claims for services furnished in a given calendar year. For the OPPS ratesetting process, our goal is to use the best available data for ratesetting so that we can accurately estimate the costs associated with furnishing outpatient services, and thus set appropriate payment rates. Ordinarily, the best available claims data is the set of data from 2 years prior to the calendar year that is the subject of rulemaking. For the CY 2022 OPPS/ASC proposed rule ratesetting, this typically would have been the set of CY 2020 calendar year outpatient claims data processed through December 31, 2020. The cost report data source is typically the Medicare hospital cost report data files from the most recently available quarterly HCRIS file as we begin the ratesetting process. For example, ordinarily, the best available cost report data used in developing the OPPS relative weights would be from cost reports beginning 3-fiscal years prior to the year that is the subject of the rulemaking. For CY 2022 OPPS ratesetting, under ordinary circumstances, that would be cost report data from HCRIS extracted in December 2020, which would contain many cost reports ending in FY 2020 based on each hospital's cost reporting period.

As discussed in section I.F. of the FY 2022 IPPS/LTCH proposed rule and in the CY 2022 OPPS proposed rule, there are a number of issues related to the use of the standard hospital data we would otherwise use for purposes of CY 2022 ratesetting because data from the applicable time period would include the effects of the COVID–19 PHE (86 FR 25086 through 25090). Even though the specific data elements might be slightly different between the inpatient and outpatient hospital settings, the same questions and challenges exist for hospital data from CY/FY 2020. Some of the issues are focused on the source data and the degree to which the utilization of services and cost patterns found in them are affected by the PHE. Other issues are more prospective in nature and concern whether hospital claims data from this time period might be consistent with our expectations for the prospective year, particularly in a changing environment with regards to COVID–19 vaccinations and treatment.

In the FY 2022 IPPS proposed rule, we proposed to use FY 2019 data for FY 2022 IPPS ratesetting based on our determination that the FY 2019 data would be more representative of FY 2022 inpatient hospital experience than the FY 2020 data (86 FR 25089). In section X.E. of the CY 2022 OPPS/ASC proposed rule (86 FR 42188 through 42190) we noted that there are a number of policies that apply and interact across the IPPS and OPPS, in part because they both concern services furnished in the hospital setting. We also discussed how we have previously noted in annual rulemaking, in regards to adopting the fiscal year IPPS wage index into the OPPS, the ''inseparable, subordinate status of the HOPD within the hospital overall'' (85 FR 85908). It is in this context where inpatient and outpatient hospital departments are inherently connected to each other, as parts of the broader hospital setting overall, we identified many of the same reasons to propose to use 2019 data for 2022 ratesetting as discussed in the FY 2022 IPPS proposed rule.

In section X.E. of the CY 2022 OPPS/ASC proposed rule (86 FR 42188 through 42190) we also noted that we

observed a number of changes, likely as a result of the PHE, in the CY 2020 OPPS claims data that we would ordinarily use for ratesetting. The most significant difference compared to prior years is the decrease in the overall volume of outpatient hospital claims—with approximately 20 percent fewer claims usable for ratesetting purposes when compared to the prior year. In addition, this decrease in outpatient claims volume applied to a majority of the clinical APCs in the OPPS.

In some cases, we saw broad changes as a result of the PHE, including in the APCs for hospital emergency department and clinic visits. Among those APCs, the decrease in volume was approximately 30 percent—some of which may be related to changing practice patterns during the PHE. For example, we saw a significant increase in the use of the HCPCS code Q3014 (Telehealth originating site facility fee) in the hospital outpatient claims, with the approximately 35,000 services billed in the CY 2019 OPPS claims increasing to 1.8 million services in the CY 2020 OPPS claims. This example highlights two types of differences we see in the CY 2020 set of claims when comparing it to more typical claims data. One difference is likely due to the degree to which elective procedures/services were not performed as often during the PHE. The other difference is the result of site of service changes due to flexibilities available during the PHE.

In other cases, we saw changes in the claims data that were associated with specific services that were furnished more frequently during the PHE. For example, two notable exceptions to this decrease in claims volume between CY 2019 and CY 2020 are for APC 5731 (Level 1 Minor Procedures) and APC 5801 (Ventilation Initiation and Management). In the case of APC 5731, HCPCS code C9803 was made effective for services furnished on or after March 1, 2020 through the interim final rule with comment period titled ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (85 FR 27602 through 27605) to describe COVID–19 specimen collection. In the CY 2020 claims, HCPCS C9803 has 1,023,957 single claims available for cost modeling, representing approximately 93 percent of claims used to model the APC cost. While in some cases this would be appropriate in establishing the APC cost, we generally would not expect the same volume of the procedure in the CY 2022 OPPS because we anticipate that specimen collection for COVID–19 testing may be significantly lower than it was in CY 2020. Similarly, the estimated increase in the geometric mean cost of APC 5801 based on the CY 2020 claims data may not be predictive of CY 2022 costs for APC 5801 if there is less use of this service in CY 2022 than in CY 2020.

As a result of a number of COVID–19 PHE-related factors, including the changes in services potentially related to the COVID–19 PHE, the significant decrease in volume suggesting that patients may have been deferring elective care during CY 2020, the changes in APC relative weights for services, and the increasing number of Medicare beneficiaries vaccinated against COVID–19, we believed that CY 2020 data were not the best overall approximation of expected outpatient hospital services in CY 2022. Instead we believed that CY 2019 data, as the most recent complete calendar year of data prior to the COVID–19 PHE, were a better approximation of expected CY 2022 hospital outpatient services.

In the CY 2022 OPPS/ASC proposed rule, we also analyzed the extent to which the decision to use CY 2019 or CY 2020 claims data as the basis for ratesetting differentially impacts the CY 2022 OPPS rates. To do this, we estimated the difference in case-mix under the CY 2019-based weights and the CY 2020-based weights if the CY 2022 outpatient experience ended up being the reverse of the assumption made when calculating that set of relative weights. In other words, we compared estimated case-mix calculated under four different scenarios. For the CY 2019-based weights, we calculated the case-mix using claims from the CY 2019-based claims extract as an approximation of the actual CY 2022 experience (Scenario A), and using claims from the CY 2020 based claims extract as an approximation of the actual CY 2022 experience (Scenario B). For the CY 2020-based weights, we calculated the case-mix using claims from the CY 2020 claims based extract as an approximation of the actual CY 2022 outpatient experience (Scenario C), and using claims from the CY 2019 claims based extract as an approximation of the actual CY 2022 experience (Scenario D). The results are shown in the following Table 51.

TABLE 51: ESTIMATED IMPACT OF CLAIMS BASED ASSUMPTIONS FOR CY 2022 OUTPATIENT EXPERIENCE

Scenario	Assumed CY 2022 Experience for Relative Weights	Actual CY 2022 Experience	Case-mix	Assumption Matched Experience	Percent change in case-mix if Mismatch between Assumption and Actual Experience
A	CY 2019	CY 2019	4.620	Yes	
B	CY 2019	CY 2020	5.056	No	0.10%
C	CY 2020	CY 2020	5.051	Yes	
D	CY 2020	CY 2019	4.600	No	-0.44%

In Scenario A and Scenario C, there is no differential impact as a result of a less accurate assumption made when the OPPS relative weights were calculated: The CY 2022 outpatient experience matches the assumption made when the OPPS relative weights were calculated. In Scenario B and Scenario D, the actual experience is the reverse of the assumption used when the OPPS relative weights were calculated.

In Scenario B, when the CY 2019-based weights were used, but the CY 2022 outpatient experience turns out to be more similar to CY 2020 claims data, the less accurate assumption slightly affects the calculated case-mix, by 0.1 percent. This can be seen by comparing the modeled case mix under Scenario B (5.056) with the modeled case-mix under Scenario C (5.051). In other words, if we use the CY 2019-based weights and CY 2022 outpatient

experience turns out to be more similar to the CY 2020 data, then the modeled case-mix is slightly lower than if we had accurately used the CY 2020-based weights. This suggests that, while there is some impact from using the CY 2019 data if CY 2022 outpatient service utilization ends up being more similar to CY 2020 utilization, that impact would be limited.

In Scenario D, where the CY 2020-based weights were used, but the CY 2022 outpatient experience turns out to be more similar to CY 2019 claims data, this inaccurate assumption has a somewhat more significant effect. In this case, the modeled case-mix is −0.44 percent lower than it would be if we had correctly assumed that CY 2022 outpatient services utilization would be more like CY 2019 than CY 2020. This can be seen by comparing the modeled case-mix under Scenario D (4.600) to the modeled case-mix under Scenario A (4.620). In other words, if we use the CY 2020-based weights and the CY 2022 outpatient experience turns out to be more similar to CY 2019 data, the modeled case-mix is −0.44 percent lower than if we had used the CY 2019-based weights.

In addition to our expectation that CY 2019 is a more likely approximation of the CY 2022 outpatient experience for the reasons discussed earlier, the previous analysis indicates that the differential effect of making an incorrect assumption about which year's data to use to set the CY 2022 OPPS relative weights is more limited if the CY 2019-based weights are used than it is if the CY 2020-based weights are used. While CY 2022 outpatient hospital services data is unlikely to look exactly like either CY 2019 data or CY 2020 data, we believe that it will be more similar to a standard year (not having the effects of the PHE) as pandemic-related issues decline and more of the U.S. population is vaccinated against COVID–19.

Consistent with the proposal to use CY 2019 claims data in establishing the CY 2022 OPPS rates, we also proposed to use cost report data from the same set of cost reports we originally used in final rule 2021 OPPS ratesetting, where we ordinarily would have used the most updated available cost reports available in HCRIS in determining the proposed CY 2022 OPPS APC relative weights (as discussed in greater detail in section II.E. of the CY 2022 OPPS/ASC proposed rule (86 FR 42053)). As discussed previously, if we were to proceed with the standard ratesetting process of using updated cost reports, we would have used approximately 1,000 cost reports with the fiscal year ending in CY 2020 based on each hospital's cost reporting period. We note that Medicare outpatient claims data and cost report data from the HCRIS file are examples of data sources for which we discussed the proposed use of CY 2019 data for CY 2022 OPPS ratesetting. While we are generally using CY 2019 claims data and the data components related to it in establishing the CY 2022 OPPS, we noted in the CY 2022 OPPS/ASC proposed rule the specific cases where we used updated information, such as the ASP data used in determining drug packaging status discussed in section V. of the CY 2022 OPPS/ASC proposed rule (86 FR 42116).

We also considered the alternative of continuing with our standard process of using the most updated claims and cost report data available. To facilitate comment on the alternative proposal for CY 2022, we made available the cost statistics and addenda utilizing the CY 2020 data we would ordinarily have provided in conjunction with the CY 2022 OPPS/ASC proposed rule. We provided a file comparing the budget neutrality and certain other ratesetting adjustments calculated under our proposal with those adjustments calculated under this alternative approach. Finally, we made available other proposed rule supporting data files based on the use of the CY 2020 data that we ordinarily would have provided, including: The OPPS Impact File, cost statistics files, addenda, and budget neutrality factors. We refer the reader to the CMS website for the CY 2022 OPPS/ASC proposed rule for more information on where these supplemental files may be found.

We note that the CY 2022 OPPS/ASC proposed rule appeared in the **Federal Register** on August 4, 2021. In the FY 2022 IPPS/LTCH PPS final rule, which appeared in the August 13, 2021 issue of the **Federal Register**, CMS finalized a policy to use FY 2019 MedPAR data in FY 2022 IPPS ratesetting (rather than FY 2020 MedPAR data) after consideration of public comments, the vast majority of which supported CMS's proposal to use the FY 2019 data for FY 2022 ratesetting for circumstances where the FY 2020 data is significantly impacted by the COVID–19 PHE. Similar to the comments received on the FY 2022 IPPS proposed rule, we received broad support from commenters with many agreeing that CY 2019 claims data would likely be more similar to the CY 2022 outpatient experience.

Comment: Commenters supported the use of CY 2019 claims in CY 2022 OPPS ratesetting, agreeing that the billing patterns found in the CY 2019 claims data would better approximate the outpatient utilization and costs in the CY 2022 OPPS, due to the effect of the PHE on the CY 2020 claims. A commenter noted challenges during the PHE such as increasing labor costs and suggested that an interim wage index adjustment factor be applied. Several stakeholders agreed with using CY 2019 claims for CY 2022 OPPS ratesetting, but noted that their support applied specifically for the CY 2022 OPPS, as similar policies for future years would need to be evaluated separately.

Response: We appreciate the commenters' support for our proposal to use CY 2019 claims in CY 2022 OPPS ratesetting as a result of the impact of the PHE on CY 2020 claims data. We note that we are finalizing the use of CY 2019 claims data in CY 2022 OPPS ratesetting.

With regards to the request for an interim wage index adjustment factor, we currently do not believe an interim wage index adjustment factor is necessary. The wage index that we would apply in the CY 2022 OPPS is not affected in the same way as claims and cost report data due to the PHE, as a result of being on a longer data delay. As cost report information becomes available that reflects changes in labor costs and wage index inputs, we will continue to review and include as appropriate in the OPPS. For more detail regarding the OPPS wage index policy, please see section II.C. of this final rule with comment period. We note that the final policy to use CY 2019 claims data for OPPS ratesetting specifically applies to the CY 2022 OPPS, and we will continue to monitor the claims and cost report data available and their appropriateness for future OPPS ratesetting, as the PHE continues.

Comment: Certain commenters supported the use of CY 2019 claims data for broader OPPS ratesetting but requested specific exceptions that would allow for the use of CY 2020 claims. These suggested exceptions included requests to use:

- CY 2020 claims data for ratesetting purposes for certain HCPCS codes that only have volume or significant volume in the CY 2020 claims but not in the 2019 claims data;
- CY 2020 claims data for establishing the CY 2022 OPPS relative weights for specific APC series;
- CY 2020 claims data for contextual purposes where CY 2019 claims are unavailable to make APC assignments, but to continue to use CY 2019 claims data for broader ratesetting; and
- Either CY 2019 or CY 2020 claims data in identifying which procedures receive device intensive status and to

use the higher of the device offsets between the 2 years of claims data.

Response: We appreciate the commenters' input in determining what data is most appropriate for developing the CY 2022 OPPS relative payment weights. We recognize that there are two important distinct issues raised by these unique requests: (1) The integrity of the OPPS relative payments weights based on the data used, and (2) data availability for ratesetting, particularly as there is different information available in each of the claims and cost report datasets based on the time frame of data they include.

In reviewing the CY 2019 and CY 2020 claims data available for developing the CY 2022 OPPS rates, we noted that we believed the CY 2019 claims would be more reflective of our expectation of the CY 2022 outpatient experience. We do not believe it is appropriate to selectively choose which claims year's data are included or not in establishing the CY 2022 relative payment weights. We note that the relative cost of services used in developing the OPPS relative payment weights is a fundamental part of the OPPS and choosing which claims to use when both CY 2019 and CY 2020 claims are broadly available may inappropriately distort certain components of the OPPS. Further, the choice of different time frames when establishing the claims dataset would raise additional concerns around data consistency and how to mitigate their effects, which may be outsized as a result of the COVID–19 PHE. Potential additional adjustment factors would need to be applied for aspects such as charge inflation, volume adjustments, and CCR adjustments similar to how they are applied for other components of the OPPS, for example, outlier payments. The OPPS relative payment weights affect the budget neutrality calculations because the volume and estimated relative costs of services comprise the budget neutral model. If actual CY 2019 claims were used in some cases and CY 2020 claims in others, we might then inadvertently over or underweight volume or estimated cost, both of which distort not just the specific OPPS payment rates for which they are used but also those of all other services within the budget neutrality model. Based on these data integrity concerns, we continue to believe using CY 2019 claims data—and CY 2019 claims data alone—in establishing the CY 2022 OPPS relative payment weights to the extent possible is the best and most effective policy. We do not believe that it is appropriate to blend use of CY 2020 claims in this process.

In the CY 2022 OPPS/ASC proposed rule, we recognized that there were certain cases in which the CY 2020 claims data may provide additional information around service costs than are available in the CY 2019 claims data, and therefore, may be the best data available for ratesetting. For example, we proposed to make an exception for 11 specific device intensive procedures as described in section IV.B.2. of the CY 2022 OPPS/ASC proposed rule (86 FR 42114) in establishing the procedures' device offsets. In these instances, procedures were previously assigned a default device offset percentage of 31 percent or a device offset percentage based on claims from a clinically similar code, and focusing solely on CY 2019 claims data would yield no changes. However, we recognized that if CY 2020 claims information were available and provided more specific context around device offsets, this updated data would yield better and potentially more specific device offset assignments than the default or clinically similar codes. For more detailed discussion around device intensive status and device offsets, please see section IV.B. of this final rule with comment period.

Along those lines, while we do not believe that it is generally appropriate to include actual CY 2020 OPPS claims data in the process of calculating the OPPS relative weights, we believe that in certain cases it is appropriate to use that cost information as contextual information for APC and device offset assignments in the CY 2022 OPPS. That is, while CY 2019 claims data are more representative of our expectation of the CY 2022 outpatient experience, in cases where there are no CY 2019 claims data available, the CY 2020 claims data may provide additional updated information around the estimated costs for specific services. Therefore, we are establishing an additional limited exception in this final rule with comment period where we will review CY 2020 claims data based on commenter requests and identification of areas where they believe the CY 2020 claims justify alternative placement, if no significant CY2019 claims data is available, as part of our review process for determining CY 2022 APC assignment. It has been our policy for updating OPPS rates annually to use the best available data for ratesetting, and we believe in certain limited, specific circumstances the CY 2020 claims data are the best available for setting CY 2022 rates. We note that throughout this rule, and particularly in section III.C. of this final rule with comment period, where we review the APC-specific policies, we discuss where we have reviewed the CY 2020 claims as part of our evaluation of data for the CY 2022 APC assignments.

With regards to the request that we apply the device intensive policy and device offset calculation based on the higher calculation between that determined by the CY 2019 or CY 2020 claims data, we believe that in cases where claims are available from both years that the CY 2019 claims remain more reflective of actual expected outpatient experience. Based on the issues discussed earlier in this section we believe it is appropriate to use the CY 2019 claims data for establishing the device intensive policy, with the exception of device intensive procedures for which CY 2020 claims remain the only data source. For a more detailed discussion of the CY 2022 device intensive policy and the limited exceptions in which CY 2020 claims data will be used for those purposes, please see section IV.B. of this final rule with comment period.

After consideration of the public comments received, we are finalizing the proposal to use CY 2019 claims data in CY 2022 OPPS ratesetting with modification to allow for review of the CY 2020 claims in determining CY 2022 APC placements based on commenter request and where CY 2019 claims data are unavailable. In addition, we note that we are finalizing the exception to allow for CY 2020 claims data for device offset assignments for the 11 codes for which we proposed exceptions, as discussed in more detail in section IV.B. of this final rule with comment period.

F. Separate Payment in CY 2022 for the Device Category, Drugs, and Biologicals With Transitional Pass-Through Payment Status Expiring Between December 31, 2021 and September 30, 2022

In the CY 2021 OPPS/ASC final rule (85 FR 86012 through 86013), we discussed the public comments we received in response to the comment solicitation we included in the CY 2021 OPPS/ASC proposed rule regarding whether we should utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to provide separate payment for some period of time after pass-through status ends for devices with expiring pass-through status in order to account for the period of time that utilization for the devices was reduced due to the PHE.[197] Although we only solicited comments on use of our equitable adjustment authority to pay separately for devices with pass-through status during the PHE, we received public comments both suggesting that drugs, biologicals, and biosimilar biological products with pass-through status during the same time period should also be subject to an adjustment to extend the pass-through period for those products and pointing out that most of these products continue to be separately paid after their pass-through status expires, and therefore, it would be unnecessary to utilize the equitable adjustment authority to ''extend'' pass-through status for these products.

As discussed elsewhere in section X.E. of the CY 2022 OPPS/ASC proposed rule (86 FR 42188 through 42190) and section I.F. of the FY 2022 IPPS/LTCH proposed rule (86 FR 25211 through 25212), our goal is to use the best available data for ratesetting. Ordinarily, the best available claims data is the set of data from 2 years prior to the calendar year that is the subject of rulemaking, and accordingly, we would have used claims data from CY 2020 for calculating proposed rates for the CY 2022 OPPS/ASC proposed rule. As noted in section X.E., however, we proposed to use CY 2019 claims data in establishing the CY 2022 OPPS rates and to use cost report data from the same set of cost reports originally used in the final rule for 2021 OPPS ratesetting. We recognize that due to the effects of the PHE, the CY 2020 claims data may not be the best available data for ratesetting, including for purposes of ratesetting for devices, drugs, and biologicals for which pass-through status expires between December 31, 2021 and September 30, 2022.

For this reason, and after consideration of the public comments we received in response to the comment solicitation included in the CY 2021 OPPS/ASC proposed rule (85 FR 48862), we proposed a one-time equitable adjustment under section 1833(t)(2)(E) of the Act to continue separate payment for the remainder of CY 2022 for devices, drugs, and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022. We have consistently explained that transitional pass-through payment for drugs, biologicals, and devices is intended as an interim measure to allow for adequate payment of certain new technology while we collect the necessary data to incorporate the costs for these items into the procedure APC rate (66 FR 55861). We believe an equitable adjustment to continue separate payment for devices, drugs, and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022 is necessary to ensure that we have full claims data from CY 2021 with which to set payment rates beginning in CY 2023. We also believe it is necessary to pay separately for these products in CY 2022 in a manner that mimics continued pass-through status, rather than having to set rates and make APC assignments and packaging decisions for these products for CY 2022 based on data from CY 2020, which we do not believe is the best available data for this purpose.

For those drugs, biologicals and the device for which payment would be packaged following expiration of their pass-through status, we believe providing separate payment for up to a full year in CY 2022 is warranted to ensure there is a full year of data for ratesetting, including to ensure appropriate APC assignments for the services with which these products are billed. For drugs and biologicals that would generally remain separately payable after their pass-through status expires, we believe providing separate payment for up to a full year in CY 2022 is necessary to ensure that these drugs and biologicals would, in fact, be separately payable when their pass-through status expires or that their payment should be packaged if we determine that the drug's cost is below the per-day packaging threshold. Specifically, for threshold-packaged drugs and biologicals, CMS requires current, appropriate data to determine whether the drug should be packaged and then to determine the impact of that packaging on the associated service rates. We also believe separate payment in CY 2022 is necessary to ensure we have sufficient data in the event payment for the drug is packaged with payment for a primary C–APC service. Finally, consistent with our goal of ensuring that the equitable adjustment provides separate payment for drugs and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022 to mimic pass-through payment to the extent possible, we proposed that separately payable drugs and biologicals that are eligible for this adjustment would not be paid the proposed reduced amount of ASP minus 22.5 percent when they are acquired under the 340B program, and would generally continue to be paid ASP+6 percent for the duration of the time period during which the adjustment applies.

We explained that under our proposal, the device category, drugs, and biologicals that would be affected were as follows. One device category, HCPCS code C1823 (Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads), would receive adjusted payment equivalent to an additional four quarters of device pass-through status. There are 27 drugs and biologicals whose pass-through payment status expires between December 31, 2021 and September 30, 2022. Based on CY 2020 data, payment for three of the 27 drugs and biologicals would otherwise be packaged after the expiration of their pass-through status. The remaining 24 drugs and biologicals would be paid separately and would otherwise receive reduced payment at the proposed rate of ASP minus 22.5 percent when they are acquired under the 340B program.

We explained that there are currently six drugs and one device category whose pass-through payment status will expire on December 31, 2021, nine drugs and three biologicals whose pass-through status will expire on March 31, 2022, seven drugs whose pass-through status will expire on June 30, 2022, and two drugs whose pass-through payment status will expire on September 30, 2022. Because pass-through status can expire at the end of a quarter, we proposed that the adjusted payment would be made for between one and four quarters, depending on when the pass-through period expires for the

[197] On January 31, 2020, HHS Secretary Azar determined that a PHE exists retroactive to January 27, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d) in response to COVID–19, and on April 21, 2020 Secretary Azar renewed, effective April 26, 2020, and again effective July 25, 2020, the determination that a PHE exists. On March 13, 2020, the President of the United States declared that the COVID–19 outbreak in the U.S. constitutes a national emergency, retroactive to March 1, 2020.

device category, drug, or biological. In particular, we proposed that separate payment would be made a full year for the device category and six drugs for which pass-through status will expire on December 31, 2021, three quarters for the twelve drugs and biologicals for which pass-through status will expire on March 31, 2022, two quarters for the seven drugs for which pass-through status will expire on June 30, 2022, and one quarter for the two drugs for which pass-through status will expire on September 30, 2022.

Table 52 lists pass-through drugs, biologicals and the device category that we proposed would receive adjusted separate payment, their pass-through payment period effective dates and end dates, as well as the number of quarters of separate payment equivalent to an extension of pass-through status that we proposed each drug or device category would receive.

BILLING CODE 4120–01–P

TABLE 52: DEVICE CATEGORY, DRUGS, AND BIOLOGICALS WITH EXPIRING PASS-THROUGH STATUS THAT WOULD RECEIVE SEPARATE PAYMENT FOR ONE TO FOUR QUARTERS IN CY 2022

HCPCS Code	Long Descriptor	Pass-Through Status Effective Date	Pass-Through Status Expiration Date	Proposed Adjustment Equivalent to an Extension of Pass-through Status (number of quarters)
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads)	01/01/2019	12/31/2021	4
A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	01/01/2019	12/31/2021	4
J0222	Injection, Patisiran, 0.1 mg	01/01/2019	12/31/2021	4
J0291	Injection, plazomicin, 5 mg	01/01/2019	12/31/2021	4
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	01/01/2019	12/31/2021	4
J2798	Injection, risperidone, (perseris), 0.5 mg	01/01/2019	12/31/2021	4
J9204	Injection, mogamulizumab-kpkc, 1 mg	01/01/2019	12/31/2021	4
J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	04/01/2019	03/31/2022	3
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	04/01/2019	03/31/2022	3
J0642	Injection, levoleucovorin 0(khapzory), 0.5 mg	01/01/2020	03/31/2022	3
J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	04/01/2019	03/31/2022	3
J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	04/01/2019	03/31/2022	3
J3245	Injection, tildrakizumab, 1 mg	04/01/2019	03/31/2022	3

HCPCS Code	Long Descriptor	Pass-Through Status Effective Date	Pass-Through Status Expiration Date	Proposed Adjustment Equivalent to an Extension of Pass-through Status (number of quarters)
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	04/01/2019	03/31/2022	3
J9119	Injection, cemiplimab-rwlc, 1 mg	04/01/2019	03/31/2022	3
J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	04/01/2019	03/31/2022	3
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	04/01/2019	03/31/2022	3
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	04/01/2019	03/31/2022	3
Q5111	Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	04/01/2019	03/31/2022	3
C9047	Injection, caplacizumab-yhdp, 1 mg	07/01/2019	06/30/2022	2
J0121	Injection, omadacycline, 1 mg	07/01/2019	06/30/2022	2
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	07/01/2019	06/30/2022	2
J1303	Injection, ravulizumab-cwvz, 10 mg	07/01/2019	06/30/2022	2
J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	07/01/2019	06/30/2022	2
J9210	Injection, emapalumab-lzsg, 1 mg	07/01/2019	06/30/2022	2
J9269	Injection, tagraxofusp-erzs, 10 micrograms	07/01/2019	06/30/2022	2
J3111	Injection, romosozumab-aqqg, 1 mg	10/01/2019	09/30/2022	1
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	10/01/2019	09/30/2022	1

BILLING CODE 4120–01–C

In the CY 2022 OPPS/ASC proposed rule we solicited comments on our proposal to utilize our equitable adjustment authority to pay separately for the remainder of CY 2022 for the device category, drugs, and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022.

Comment: The overwhelming majority commenters generally supported our proposal to utilize our equitable adjustment authority to pay separately for between one and four

quarters for certain devices, drugs, and biologicals whose pass-through status will expire between December 31, 2021 and September 30, 2022. One commenter stated their support for CMS' proposal and added that separate payment for items that will soon lose pass-through status will help ensure beneficiary access to innovative therapies. The commenter added that the COVID–19 pandemic has severely skewed hospital utilization data that is necessary to establish payment rates under the OPPS.

Response: We thank the commenters for their support for our proposal.

Comment: Multiple commenters requested changes to our proposed equitable payment adjustment to either expand or limit its scope. One commenter strongly supported CMS's policy that makes radiopharmaceuticals eligible for pass-through status and added that CMS should apply this pass-through period extension to all radiopharmaceuticals with pass-through status during the COVID–19 PHE. Several other commenters asked that the proposed pass-through extension be expanded to include all pass-through devices, drugs, and biologicals that currently have pass-through status. One commenter acknowledged the requirement in section 1833(t)(2)(E) that equitable adjustments be budget neutral, but nonetheless suggested that to the extent possible, CMS should consider whether the adjustment to continue separate payment could be made in a non-budget neutral manner to minimize the impact of this policy on payment for other items and services under the OPPS.

Another commenter stated that if CMS finalizes use of its equitable adjustment authority to continue separate payment for certain pass-through products, it should not do so for products that have already had more than 3 years of pass-through status. One commenter stated that CMS should not use its equitable adjustment authority to provide separate payments for pass-through drugs, biologicals, and biosimilar biological products after pass-through status expires for these products where the products would continue to receive separate payment under our existing policy. Multiple commenters asked for our proposal to be applied to specific products or HCPCS codes; in some cases the commenters asserted that products on pass-through status experienced claims processing challenges that impacted data collection, ratesetting, and beneficiary access because of the effects of the PHE.

Response: We thank the commenters for the information provided in response to our proposal to utilize our equitable adjustment authority to pay separately for the remainder of CY 2022 for the device category, drugs, and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022. We note that our proposal was limited to an extension for those drugs, biologicals, and devices for which pass-through status is ending between December 31, 2021 and September 30, 2022 and for which we would otherwise use data from CY 2020 for ratesetting for these products in CY 2022. We agree that this proposal should not be applied to pass-through products that have previously received more than three years of pass-through status, however, to our knowledge no such product for which we proposed to provide continued separate payment has already had more than three years of pass-through status. In response to commenters' request that we implement the proposed adjustment in a non-budget neutral manner, we note that the equitable adjustment authority at section 1833(t)(2)(E) requires that any adjustments made under it be budget neutral.

Furthermore, we note that some commenters alleged that CMS is effectively removing 1 year of pass-through data with their decision to use CY 2019 as opposed to CY 2020 data for ratesetting. We note that CMS is required to provide between 2 and 3 years of pass-through payment status and that each drug, device and biological will have had at least 3 years of pass-through status under our proposal. We will continue to assess this issue as it relates to pass-through status and ratesetting in future years.

After considering the public comments, we are finalizing our proposal to utilize our equitable adjustment authority to pay separately for the remainder of CY 2022 for the device category, drugs, and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022.

XI. CY 2022 OPPS Payment Status and Comment Indicators

A. CY 2022 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system, and also whether particular OPPS policies apply to the code.

For CY 2022, we did not propose to make any changes to the existing definitions of status indicators that were listed in Addendum D1 to the CY 2021 OPPS/ASC final rule with comment period available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

We did not receive any comments on the proposed definitions of the OPPS payment status indicators or their definitions for 2022. We believe that the existing definitions of the OPPS status indicators will continue to be appropriate for CY 2022. Therefore, we are finalizing those definitions without modification for CY 2022.

The complete list of payment status indicators and their definitions that would apply for CY 2022 is displayed in Addendum D1 to the CY 2022 OPPS/ASC final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

CY 2022 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to the CY 2022 OPPS/ASC final rule with comment period, which are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

B. CY 2022 Comment Indicator Definitions

In the CY 2022 OPPS/ASC proposed rule, we proposed to use four comment indicators for the CY 2022 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2021 and we proposed to continue their use in CY 2022. The proposed CY 2022 OPPS comment indicators are as follows:

- ''CH''—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NC''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will *not* be accepted on the final APC assignment for the new code.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year,

interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

• ''NP''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the OPPS comment indicators for CY 2022 are listed in Addendum D2 to the CY 2022 OPPS/ASC final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

We did not receive any comments on the proposed definitions of the OPPS comment indicators for 2022.

We believe that the existing CY 2021 definitions of the OPPS comment indicators continue to be appropriate for CY 2022. Therefore, we are finalizing those definitions without modification for CY 2022.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. We are including this section to make stakeholders aware of certain MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2021 report.

A. OPPS Payment Rates Update

The March 2021 MedPAC ''Report to the Congress: Medicare Payment Policy,'' recommended that Congress update Medicare OPPS payment rates by 2 percent, with the difference between this and the update amount specified in current law to be used to increase payments in a new suggested Medicare quality program, the ''Hospital Value Incentive Program (HVIP).'' We refer readers to the March 2021 report for a complete discussion of these recommendations.[198] We appreciate MedPAC's recommendations, but as MedPAC acknowledged in its March 2021 report, the Congress would need to change current law to enable us to implement its recommendations. Comments received from MedPAC for other OPPS policies are discussed in the applicable sections of this final rule with comment period.

B. ASC Conversion Factor Update

In the March 2021 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC found that, based on its analysis of indicators of payment adequacy, the number of ASCs had increased, beneficiaries' use of ASCs had increased, and ASC access to capital has been adequate.[199] As a result, for CY 2022, MedPAC stated that payments to ASCs are adequate and recommended that, in the absence of cost report data, no payment update should be given for CY 2022 (that is, the update factor would be zero percent).

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59079), we adopted a policy, which we codified at 42 CFR 416.171(a)(2), to apply the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years. We refer readers to the CY 2019 OPPS/ASC final rule with comment period for complete details regarding our policy to use the productivity-adjusted hospital market basket update for the ASC payment system for CY 2019 through CY 2023. Therefore, consistent with our policy for the ASC payment system, as discussed in section XIII.G. of the CY 2022 OPPS/ASC proposed rule, we proposed to apply a 2.3 percent productivity-adjusted hospital market basket update factor to the CY 2021 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2022 ASC payment amounts. The final CY 2022 ASC conversion factor for ASCs meeting quality reporting requirements and the final hospital market basket update factor are discussed in section XIII. of this final rule with comment period.

C. ASC Cost Data

In the March 2021 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC recommended that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers, and that CMS could use ASC cost data to examine whether an existing Medicare price index is an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed. Further, MedPAC suggested that CMS could limit the scope of the cost reporting system to minimize administrative burden on ASCs and the program but should make cost reporting a condition of ASC participation in the Medicare program.[200]

While we recognize that the submission of cost data could place additional administrative burden on most ASCs, and we did not propose any cost reporting requirements for ASCs in the CY 2022 OPPS/ASC proposed rule, we are interested in public comment on methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs. Such cost data would be beneficial in establishing an ASC-specific market basket index for updating payment rates under the ASC payment system.

Comment: MedPAC reiterated its previous recommendation and suggested that CMS should collect cost data from ASCs to set ASC payment rates that accurately reflect the costs of efficient providers and eliminate payment misalignments that exist as well as inform decisions about annual payment rate updates to the ASC payment system. MedPAC stated that it is feasible for ASCs to provide cost information and that smaller providers, such as hospices, currently provide such information to CMS. MedPAC suggested CMS could create a streamlined process of limited cost data with limited cost variables rather than a formal, and more time-consuming, cost report.

Other commenters suggested that CMS work closely with industry associations in developing the methodology for cost reporting. An ASC industry association suggested that CMS recognize that cost experience can differ greatly depending on factors such as the size of the facility, location, and the specialties served. Further, the ASC association suggested that if CMS were to collect ASC cost reports that we consider developing a single market

[198] Medicare Payment Advisory Committee. March 2021 Report to the Congress. Chapter 3: Hospital Inpatient and outpatient services, pp.81–82. Available at: *http://medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf?sfvrsn=0*.

[199] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.147. Available at: *http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0*.

[200] Medicare Payment Advisory Committee. March 2021 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.157. Available at: *http://medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf?sfvrsn=0*.

basket update that could be applied to both ASCs as well as HOPDs.

Response: We appreciate MedPAC's comment regarding cost submission and feedback submitted by other commenters and will take them into consideration in future rulemaking. While we did not propose any cost reporting requirements for CY 2022, the comments we did receive are helpful as we continue to explore methods for obtaining cost information in a manner that does not place undue burden on ASCs.

Comments received from MedPAC for other ASC payment system policies are discussed in the applicable sections of this final rule with comment period. The full March 2021 MedPAC Report to Congress can be downloaded from MedPAC's website at: *http://www.medpac.gov*.

XIII. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CYs 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, and 2021 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through 59080; 84 FR 61370 through 61410, and 85 FR 86121 through 86179, respectively).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under §§ 416.2 and 416.166 of the Medicare regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, are not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, are not only able to be reported using a CPT unlisted surgical procedure code, and are not otherwise excluded under § 411.15.

In previous years, we identified surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, that we would not expect to require an overnight stay when performed in ASCs, and that are separately paid under the OPPS (72 FR 42478).

Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. As provided at § 416.164(b), we make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) Brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; (5) certain radiology services for which separate payment is allowed under the OPPS; and (6) non-opioid pain management drugs that function as a supply when used in a surgical procedure. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, and we use quarterly change requests (CRs) to update services paid for under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the American Medical Association (AMA) and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process is used to update HCPCS and CPT codes, which we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

3. Definition of ASC Covered Surgical Procedures

Since the implementation of the ASC prospective payment system, we have historically defined a ''surgical'' procedure under the payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42478). We also have included as ''surgical,'' procedures that are described by Level II HCPCS codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range.

As we noted in the August 7, 2007 final rule that implemented the revised ASC payment system, using this definition of surgery would exclude from ASC payment certain invasive,

''surgery-like'' procedures, such as cardiac catheterization or certain radiation treatment services that are assigned codes outside the CPT surgical range (72 FR 42477). We stated in that final rule that we believed continuing to rely on the CPT definition of surgery is administratively straightforward, is logically related to the categorization of services by physician experts who both establish the codes and perform the procedures, and is consistent with a policy to allow ASC payment for all outpatient surgical procedures.

However, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), after consideration of public comments received in response to the CY 2019 OPPS/ASC proposed rule and earlier OPPS/ASC rulemaking cycles, we revised our definition of a surgical procedure under the ASC payment system. In that final rule, we defined a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42476), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we determined met the general standards established in previous years for addition to the ASC CPL. These criteria included that a procedure is not expected to pose a significant risk to beneficiary safety when performed in an ASC, that standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and that the procedure is separately paid under the OPPS. In CY 2021, we revised the definition of covered surgical procedures to surgical procedures specified by the Secretary that are separately paid under the OPPS, are not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, are not only able to be reported using a CPT unlisted surgical procedure code, and are not otherwise excluded under § 411.15 (85 FR 86153). As discussed in section XIII.C.1.d. of this final rule with comment period (below), we are finalizing our proposal for CY 2022 to revise the language in the regulation text at § 416.166 and reinstate the general standards and exclusion criteria in place prior to CY 2021.

B. ASC Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised HCPCS Codes Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 ASC final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. We refer to these codes as new and revised in the CY 2022 OPPS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we proposed to solicit public comments in the CY 2022 OPPS/ASC proposed rule (and respond to those comments in the CY 2022 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2022 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2023 OPPS/ASC final rule with comment period).

We note that we sought public comments in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85866) on the new and revised Level II HCPCS codes effective October 1, 2020 or January 1, 2021. These new and revised codes were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2021 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2021 OPPS/ASC final rule with comment period. In the CY 2022 OPPS/ASC proposed rule, we stated that we will finalize the treatment of these codes under the ASC payment system in this CY 2022 OPPS/ASC final rule with comment period.

2. April 2021 HCPCS Codes for Which We Solicited Public Comments in the Proposed Rule

For the April 2021 update, there was one new CPT code and there were 11 new Level II HCPCS codes. In the April 2021 ASC quarterly update (Transmittal 10702, CR 12183, dated April 1, 2021), we added 11 new Level II HCPCS codes to the list of ASC covered surgical procedures and the list of covered ancillary services. Table 39 of the CY 2022 OPPS/ASC proposed rule displayed the new Level II HCPCS codes that were implemented April 1, 2021, along with their final payment indicators for CY 2022.

We invited public comments on the proposed payment indicators and payment rates for the new HCPCS codes that were recognized as ASC covered surgical procedures and ancillary services in April 2021 through the quarterly update CRs, as listed in Table 53. We proposed to finalize their payment indicators in this CY 2022 OPPS/ASC final rule with comment period.

We did not receive any comments on the proposed ASC payment indicator assignments for the new Level II HCPCS codes implemented in April 2021 and we are finalizing the proposed ASC payment indicator assignments for these codes, as indicated in Table 53. We note that several of the temporary drug HCPCS C-codes have been replaced with permanent drug HCPCS J-codes, effective January 1, 2022. Their replacement codes are also listed in Table 53.

The final comment indicators, payment indicators and payment rates, where applicable, for these April 2021 codes can be found in Addendum BB to this CY 2022 OPPS/ASC final rule with

comment period rule (which is available via the internet on the CMS website). The list of final ASC payment indicators and corresponding definitions can be found in Addendum DD1 to the CY 2022 OPPS/ASC final rule. These new codes that were effective April 1, 2021, were assigned to comment indicator ''NP'' in Addendum BB to the CY 2022 OPPS/ASC proposed rule to indicate that the codes were assigned to an interim APC assignment and that comments would be accepted on their interim APC assignments. Also, the list of final comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 in this final rule with comment period. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

BILLING CODE 4120–01–P

TABLE 53: NEW LEVEL II HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2021

CY 2021 HCPCS Code	CY 2022 HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 PI
A9592	A9592	Copper cu-64, dotatate, diagnostic, 1 millicurie	K2
C9074	J0224	Injection, lumasiran, 0.5 mg	K2
C9776	C9776	Intraoperative near-infrared fluorescence imaging of major extra-hepatic bile duct(s) (e.g., cystic duct, common bile duct and common hepatic duct) with intravenous administration of indocyanine green (icg) (list separately in addition to code for primary procedure)	N1
C9777	C9777*	Esophageal mucosal integrity testing by electrical impedance, transoral, includes esophagoscopy or esophagogastroduodenoscopy	J8
J1427	J1427	Injection, viltolarsen, 10 mg	K2
J1554	J1554	Injection, immune globulin (asceniv), 500 mg	K2
J7402	J7402	Mometasone furoate sinus implant, (sinuva), 10 micrograms	K2
J9037	J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	K2
J9349	J9349	Injection, tafasitamab-cxix, 2 mg	K2

*Effective January 1, 2022, the descriptor for HCPCS code C9777 has been revised to "Esophageal mucosal integrity testing by electrical impedance, transoral, includes esophagoscopy or esophagogastroduodenoscopy" to describe the service associated with performing both an MiVu test and an esophagoscopy or esophagogastroduodenoscopy test. When performed together, ASCs should report only HCPCS code C9777 and not report a separate HCPCS code for the esophagoscopy or esophagogastroduodenoscopy.

BILLING CODE 4120–01–C

3. July 2021 HCPCS Codes for Which We Solicited Public Comments in the Proposed Rule

In the July 2021 ASC quarterly update (Transmittal 10858, Change Request 12341, dated June 25, 2021), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 40 of the CY 2022 OPPS/ASC proposed rule displayed the new HCPCS codes that were effective July 1, 2021. In addition, through the July 2021 quarterly update CR, we added 11 new Category III CPT codes to the list of ASC covered ancillary services, effective July 1, 2021. These codes were listed in Table 41 of the CY 2021 OPPS/ASC proposed rule, along with the proposed comment indicators and payment indicators.

We invited public comments on the proposed comment indicators and payment indicators for the new Level II HCPCS codes newly recognized as ASC covered surgical procedures and covered ancillary services and the new Category III CPT codes for covered ancillary services beginning in July 2021 through the quarterly update CRs, as

listed in Tables 40 and 41 of the CY 2022 OPPS/ASC proposed rule. We proposed to finalize the proposed payment indicators in this final rule with comment period.

We did not receive any public comments on the proposed ASC payment indicator assignments for the new Category III CPT codes or Level II HCPCS codes implemented in July 2021 and are finalizing the proposed ASC payment indicator assignments for these codes, as indicated in Tables 54 and 55. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective January 1, 2022. Their replacement codes are listed in Table 54. The final CY 2022 payment rates for these new codes can be found in Addenda AA and BB to this final rule with comment period.

The list of final ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this final rule with comment period (which is available via the internet on the CMS website). These new codes that were effective July 1, 2021, were assigned comment indicator ''NP'' in Addendum BB to the CY 2022 OPPS/ASC proposed rule to indicate that the codes were assigned to an interim APC assignment and that comments would be accepted on those assignments. The list of final comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to the CY 2022 OPPS/ASC final rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

BILLING CODE 4120–01–P

TABLE 54: NEW LEVEL II HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2021

CY 2021 HCPCS Code	CY 2022 HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 PI
A9593	A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	K2
A9594	A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	K2
C1761	C1761	Catheter, transluminal intravascular lithotripsy, coronary	J7
C9075	J1426	Injection, casimersen, 10 mg	K2
C9076	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	K2
C9077	J0741	Injection, cabotegravir and rilpivirine, 2 mg/3 mg	K2
C9078	J1448	Injection, trilaciclib, 1 mg	K2
C9079	J1305	Injection, evinacumab-dgnb, 5mg	K2
C9080	J9247	Injection, melphalan flufenamide, 1 mg	K2
C9778	C9778	Colpopexy, vaginal; minimally invasive extra-peritoneal approach (sacrospinous)	G2
J0224	J0224	Injection, lumasiran, 0.5 mg	K2
J1951	J1951	Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg	K2
J7168	J7168	Prothrombin complex concentrate (human), kcentra, per i.u. of factor ix activity	K2
J9348	J9348	Injection, naxitamab-gqgk, 1 mg	K2
J9353	J9353	Injection, margetuximab-cmkb, 5 mg	K2
Q5123	Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg	K2

TABLE 55: NEW CATEGORY III CPT CODE FOR COVERED ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2021

CY 2021 HCPCS Code	CY 2022 HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 PI
0493T	0493T	Contact near-infrared spectroscopy studies of lower extremity wounds (eg, for oxyhemoglobin measurement)	N1
0644T	0644T	Transcatheter removal or debulking of intracardiac mass (e.g., vegetations, thrombus) via suction (e.g., vacuum, aspiration) device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed	J8
0647T	0647T	Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report	J8
0648T	0648T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	Z2
0649T	0649T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	N1
0651T	0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report	J8
0652T	0652T	Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	J8
0653T	0653T	Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple	J8
0654T	0654T	Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter	J8

CY 2021 HCPCS Code	CY 2022 HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 PI
0655T	0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging	G2
0663T	0663T	Scalp cooling, mechanical; placement of device, monitoring, and removal of device (List separately in addition to code for primary procedure)	N1

4. October 2021 HCPCS Codes for Which We Are Soliciting Public Comments in This CY 2022 OPPS/ASC Final Rule With Comment Period

In the past, we released new and revised HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period.

For CY 2022, consistent with our established policy, we proposed that the Level II HCPCS codes that will be effective October 1, 2021, would be flagged with comment indicator ''NI'' in Addendum B to this final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2022. We did not receive any public comments regarding this proposed process; and, for CY 2022, we are finalizing our proposal, without modification, to continue our established process for recognizing and soliciting public comments on new Level II HCPCS codes that become effective on October 1, 2021. We note all codes flagged with comment indicator ''NI'' in ASC Addenda.

AA and BB to this final rule with comment period, including the codes effective October 1, 2021, will be assigned an interim payment status to indicate that they are subject to public comment.

In the October 2021 ASC quarterly update (Transmittal 11004, Change Request 12451, dated September 17, 2021), we added several separately payable Level II HCPCS codes to the list of covered surgical procedures and ancillary services. We note that because many of the new drug HCPCS J codes effective October 1 have predecessor HCPCS C-codes, they are not completely new to the ASC payment system, and have been paid separately under their predecessor codes. Table 56 shows the interim ASC payment indicators for the new codes effective October 1, 2021, with no predecessor codes. The final comment indicators, payment indicators, and payment rates, where applicable, for these October 2021 codes can be found in Addendum AA and Addendum BB to this CY 2022 OPPS/ASC final rule with comment period rule (which is available via the internet on the CMS website). Because these codes were effective October 1, 2021, we were not able to include them in the CY 2022 OPPS/ASC proposed rule that appeared in the **Federal Register** on August 4, 2021. We note that the definitions for the ASC payment indicators can be found in Addendum DD1 to this final rule with comment period. In addition, the definitions for the ASC comment indicators can be found in Addendum DD2 to this final rule with comment period. We are inviting public comments in this final rule with comment period for the codes listed in Table 56 on the interim payment indicators, which would then be finalized in the CY 2023 OPPS/ASC final rule with comment period.

TABLE 56: NEW LEVEL II HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE ON OCTOBER 1, 2021

CY 2021 HCPCS Code	CY 2022 HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 PI
C1831	C1831	Personalized, anterior and lateral interbody cage (implantable)	J7
C9084	C9084	Injection, loncastuximab tesirine-lpyl, 0.1 mg	K2
J0699	J0699	Injection, cefiderocol, 10 mg	K2

BILLING CODE 4120–01–C

5. January 2022 HCPCS Codes

a. Level II HCPCS Codes for Which We Are Soliciting Public Comments in This CY 2022 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC payment system for the calendar year. We note that unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O to the CY 2022 OPPS/ASC proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules, however, the codes are flagged with comment indicator ''NI'' in ASC Addenda AA and BB to this final rule with comment period to indicate that we are assigning them an interim payment status, which is subject to public comment. Therefore, as we stated in the CY 2022 OPPS/ASC proposed rule, these Level II HCPCS codes that will be effective January 1, 2022 will be released to the public through the January 2022 ASC Update CR and included on the CMS HCPCS website and in this final rule with comment period.

In addition, for CY 2022, we proposed to continue our established policy of assigning comment indicator ''NI'' in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2022, to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We are inviting public comments in this final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2023 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Solicited Public Comments in the CY 2022 OPPS/ASC Proposed Rule

For new and revised CPT codes effective January 1, 2022, that were received in time to be included in the CY 2022 OPPS/ASC proposed rule, we proposed the appropriate payment indicator assignments, and solicited public comments on those assignments. We stated we would accept comments and finalize the payment indicators in this final rule with comment period. For those new/revised CPT codes that were received too late for inclusion of the CY 2022 OPPS/ASC proposed rule, we stated that we may either make interim final assignments in this final rule with comment period or use HCPCS G codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle.

For the CY 2022 ASC update, the new and revised Category I and III CPT codes that will be effective on January 1, 2022, can be found in ASC Addendum AA and Addendum BB to this final rule with comment period (which are available via the internet on the CMS website). The CPT codes are assigned to comment indicator ''NP'' to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year and that comments will be accepted on the proposed payment indicator. Further, we remind readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and their long descriptors for the new and revised CY 2022 CPT codes in Addendum O to the CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website) so that the public could adequately comment on our proposed payment indicator assignments. The 5-digit placeholder codes were in Addendum O to the CY 2022 OPPS/ASC proposed rule, specifically under the column labeled ''CY 2021 OPPS/ASC Proposed Rule 5-Digit Placeholder Code.'' The final CPT code numbers are included in this final rule with comment period, and can be found in Addendum AA, Addendum BB, and Addendum O.

In summary, we solicited public comments on the proposed CY 2022 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2022. Because these codes are listed in Addenda AA and Addendum BB with short descriptors only, we listed them again in Addendum O with the long descriptors. We also proposed to finalize the payment indicator for these codes (with their final CPT code numbers) in this final rule with comment period. The final payment indicator and comment indicator for these codes can be found in Addendum AA and BB to this final rule with comment period. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this final rule with comment period. These new CPT codes that will be effective January 1, 2022, were assigned to comment indicator ''NP'' in Addendum AA and BB to the CY 2022 OPPS/ASC proposed rule to indicate that the codes were assigned to an interim payment indicator and that comments would be accepted on their interim ASC payment assignments. Also, the list of comment indicators and definitions used under the ASC can be found in Addendum DD2 of this final rule with comment period. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

Finally, in Table 57 below, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC payment system.

BILLING CODE 4120–01–P

TABLE 57: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2021	HCPCS (CPT and Level II codes)	April 1, 2021	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
July 2021	HCPCS (CPT and Level II codes)	July 1, 2021	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
October 2021	HCPCS (CPT and Level II codes)	October 1, 2021	CY 2022 OPPS/ASC final rule with comment period	CY 2023 OPPS/ASC final rule with comment period
January 2022	CPT Codes	January 1, 2022	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2022	CY 2022 OPPS/ASC final rule with comment period	CY 2023 OPPS/ASC final rule with comment period

BILLING CODE 4120–01–C

C. Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC Covered Procedures List (CPL) in CY 2008 or later years that we determine are furnished predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule with payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the ASC standard ratesetting methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the ASC CPL to include all covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

Comment: A number of commenters requested that we modify our approach to incorporate PFS nonfacility PE RVUs in response to our proposal to update clinical labor pricing data in the CY 2022 PFS proposed rule. These commenters contended that our proposal to update clinical labor pricing data would cause significant declines in ASC payment for certain office-based services. The commenters recommended we delay or transition the proposed changes in nonfacility PE RVUs under the ASC payment system.

Response: We are not accepting this recommendation. While we acknowledge that certain proposals under the PFS may have a downstream impact on ASC payment rates for office-based procedures, our office-based policy is meant to achieve payment parity between the ASC and physician office settings. Therefore, we believe ASC payment rates for office-based procedures should be consistent with the PFS payment rates where nonfacility PE RVU data is available. Additionally,

under the PFS, we are finalizing a policy to update clinical labor pricing over a four-year transition. For more information on the proposed clinical labor pricing update under the PFS, see 86 FR 39118 through 39123.

(2) Changes for CY 2022 to Covered Surgical Procedures Designated as Office-Based

In developing the CY 2022 OPPS/ASC proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment (described in detail in section XIII.C.1.d. of this final rule with comment period), including their potential designation as office-based. Historically, we would also review the most recent claims volume and utilization data (CY 2020 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2020 of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight), as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2'', ''P3'', or ''R2'' in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86131 through 86139). However, as discussed in section X.E of the CY 2022 OPPS/ASC proposed rule (86 FR 42188 through 42190), given our concerns with CY 2020 claims data as a result of the PHE, we did not propose to review the most recent claims volume and utilization data from CY 2020 claims and instead we proposed not to assign permanent office-based designations for CY 2022 to any covered surgical procedure currently assigned a payment indicator of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight).

Similarly, we also proposed not to use the most recent claims volume and utilization data and other information for procedures designated as temporarily office-based and temporarily assigned one of the office-based payment indicators, specifically ''P2,'' ''P3'' or ''R2''. Instead, we proposed to continue to designate these procedures, shown in Table 58 below, as temporarily office-based for CY 2022. CPT code 0551T (Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume) is removed from Table 58 below as this code is being deleted effective January 1, 2022. The procedures we proposed to designate as temporarily office-based for CY 2022 are identified with an asterisk in Addendum AA to this final rule with comment period (which is available via the internet on the CMS website).

BILLING CODE 4120–01–P

TABLE 58: PROPOSED CY 2022 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2021 OPPS/ASC FINAL RULE

CY 2022 CPT/HCPCS Code	CY 2022 Long Descriptor	CY 2021 ASC Payment Indicator	Final CY 2022 ASC Payment Indicator*
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3	P3*
65785	Implantation of intrastromal corneal ring segments	P2	P2*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (report medication separately)	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2	R2*
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2	P2*
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2	P2*

* Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the CY 2022 PFS final rates. For a discussion of the final PFS rates, we refer readers to the CY 2022 PFS final rule.

BILLING CODE 4120–01–C

As discussed in the August 2, 2007 ASC final rule revised ASC payment system final rule (72 FR 42533 through 42535), we finalized our policy to designate certain new surgical procedures as temporarily office-based until adequate claims data are available to assess their predominant sites of service, whereupon if we confirm their office-based nature, the procedures would be permanently assigned to the list of office-based procedures. In the absence of claims data, we stated we would use other available information, including our clinical advisors' judgment, predecessor CPT and Level II HCPCS codes, information submitted by representatives of specialty societies and professional associations, and information submitted by commenters during the public comment period.

For CY 2022, we proposed to designate two new CY 2022 CPT codes for ASC covered surgical procedures as temporarily office-based. After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that the procedures listed in Table 59 would be predominantly performed in physicians' offices. We believe the procedure described by CPT code 42975

(Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic) is similar to CPT code 31505 (Laryngoscopy, indirect; diagnostic (separate procedure)) which is currently on the list of ASC covered surgical procedures and was assigned a final payment indicator of ''P3''—Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs—in CY 2021. Additionally, we believe the procedure described by CPT code 53454 (Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume) is similar to CPT code 0551T (Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume), which is currently on the list of ASC covered surgical procedures and was assigned a final payment indicator of ''R2''—Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight—for CY 2021. As such, we proposed to add CPT codes 42975 (CMS placeholder code 42XXX) and 53454 (CMS placeholder code 53XX4) in Table 59 to the list of ASC covered surgical procedures designated as temporarily office-based for CY 2022.

TABLE 59: CY 2022 PAYMENT INDICATORS FOR NEW CY 2022 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2022 CPT code	CY 2022 OPPS/ASC proposed rule 5-digit CMS placeholder code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator**
42975	42XXX	Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic	R2**
53454	53XX4	Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume	R2**

** Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2022 PFS proposed rates. For a discussion of the PFS rates, we refer readers to the CY 2022 PFS proposed rule.

Comment: One commenter recommended that we not assign office-based payment indicator ''P3'' to CPT code 64640 (Destruction by neurolytic agent; other peripheral nerve or branch) and suggested this procedure is not predominantly performed in the office setting.

Response: CPT code 64640 has been assigned permanent office-based status since CY 2008. With the exceptions of procedures assigned temporary office-based status and calendar years for which office-based procedures meet the criteria to be assigned device-intensive status, office-based procedures are not eligible to remove their office-based designation. As discussed previously, these are permanent assignments. While we acknowledge that certain office-based procedures can become more predominantly performed in higher cost settings, such as a hospital outpatient department, we do not believe this suggests that our office-based payment policy is hindering access to care for these procedures in an ASC setting.

Comment: One commenter recommended we reevaluate the permanent office-based designation for CPT code 42975. The commenter suggested that this procedure is more similar to CPT code 31546 (Laryngoscopy, direct, operative, with operating microscope or telescope, with submucosal removal of non-neoplastic lesion(s) of vocal cord; reconstruction with graft(s) (includes obtaining autograft))—a procedure that is not predominantly performed in a physician office setting.

Response: We are not accepting this recommendation. As discussed previously, we believe the procedure described by CPT code 42975 is similar to CPT code 31505 (Laryngoscopy, indirect; diagnostic (separate procedure)), which is predominantly performed in the physician office setting and is currently on the list of ASC covered surgical procedures and was assigned a final payment indicator of ''P3''—Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs—in CY 2021.

After reviewing the public comments we received, we are finalizing our proposal, without modification, to designate the procedures shown in Tables 58 and 59 above as temporarily office-based. The procedures for which the office-based designation for CY 2022 is temporary are indicated by an asterisk in Addendum AA to this final rule with

comment period (which is available via the internet on the CMS website).

b. Device-Intensive ASC Covered Surgical Procedures

(1) Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

(2) Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2022

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 590401 through 59043), for CY 2019, we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. Specifically, for CY 2019 and subsequent years, we adopted a policy that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC and involve the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2. of CY 2019 OPPS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

Based on these criteria, for 2022, we proposed to update the ASC CPL to indicate procedures that are eligible for payment according to our device-intensive procedure payment methodology, based on the proposed individual HCPCS code device-offset percentages using the CY 2019 OPPS claims and cost report data available for the CY 2022 OPPS/ASC proposed rule.

The ASC covered surgical procedures that we proposed to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2022, are assigned payment indicator ''J8'' and are included in ASC Addendum AA to the CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website). The CPT code, the CPT code short descriptor, the proposed CY 2022 ASC payment indicator, and an indication of whether the full credit/partial credit (FB/FC) device adjustment policy would apply because the procedure is designated as device-intensive are also included in Addendum AA to the proposed rule (which is available via the internet on the CMS website).

Under current policy, the payment rate under the ASC payment system for device-intensive procedures furnished with an implantable or inserted medical device are calculated by applying the device offset percentage based on the ASC standard ratesetting methodology to the OPPS national unadjusted payment based on the ASC standard ratesetting methodology to determine the device cost included in the OPPS payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We calculate the service portion of the ASC payment for device intensive procedures by applying the uniform ASC conversion factor to the service (non-device) portion of the OPPS relative payment weight for the device-intensive procedure. Finally, we sum the ASC device portion and ASC service portion to establish the full payment for the device-intensive procedure under the ASC payment system (82 FR 59409).

In past rulemaking (79 FR 66924), we have stated that the device-intensive methodology for ASCs should align with the device-intensive policies under the OPPS. Further, we have stated that we do not believe that procedures are device-intensive in one setting and not in another setting. We have heard concerns from stakeholders that our methodology does not provide device-intensive status to certain procedures even though the procedures' device offset percentages are greater than our 30 percent threshold when calculated under the standard ASC ratesetting methodology. We have also heard concerns from stakeholders that procedures designated as device-intensive under the OPPS are not assigned device-intensive status under the ASC payment system even though the procedure has significant device costs.

The different ratesetting methodologies used under the OPPS and ASC payment system can create conflicts when determining device-intensive status. For example, procedures with device offset percentages greater than 30 percent under the OPPS may not have device offset percentages greater than 30 percent when calculated under the standard ASC ratesetting methodology. Under current policy, procedures must be device-intensive in the OPPS setting to be eligible for device-intensive status under the ASC payment system. However, this methodology has caused confusion among stakeholders and has denied device-intensive status to procedures with significant device costs. While we believe that device-intensive policies under the ASC payment system should align with device-intensive policies under the OPPS, we believe device-intensive

status under the ASC payment system should, at a minimum, reflect a procedure's estimated device costs under the ASC standard ratesetting methodology. Therefore, for CY 2022 and subsequent years, we proposed to assign device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS.

Further, in situations where a procedure is designated as device-intensive under the OPPS but the procedure's device offset percentage is below the device-intensive threshold under the standard ASC ratesetting methodology, we believe that deference should be given to the OPPS designation to address this conflict in status. Since the comprehensive ratesetting methodology under the OPPS packages a greater amount of non-device costs into the primary procedure and is typically able to use a greater number of claims in its ratesetting methodology, we believe that if a device receives OPPS device-intensive status, the device should also be device-intensive in the ASC setting, given that fewer non-device costs are generally packaged into a procedure's cost under the ASC methodology compared to the OPPS methodology. Therefore, for CY 2022 and subsequent years, we proposed that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent.

We solicited comments on our proposed changes related to designating surgical procedures as device-intensive under the ASC payment system.

Comment: Many commenters supported our proposed changes related to designating surgical procedures as device-intensive under the ASC payment system. One commenter requested that we allow for the continuation of the default device offset percentage of 31 percent for procedures with fewer than 100 claims if the device offset percentage under the comprehensive and standard ratesetting methodology is less than 30 percent.

Response: We thank the commenters for their support of our proposal. We do not believe it would be appropriate to eliminate our device offset calculation for procedures with fewer than 100 claims because it is not our general policy to judge the accuracy of hospital charging and hospital cost reporting practices for purposes of ratesetting. Therefore, we will continue to rely on available claims data for determining device offset percentages for procedures with fewer than 100 claims.

Comment: Many commenters requested that we apply the device offset percentage for several new procedures with the predecessor code's device offset percentage based on CY 2019 claims data. These procedures include:

- The predecessor CPT code 0191T in assigning the device offset percentage for CPT code 66989 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (*e.g.,* irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (*e.g.,* iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more);
- The predecessor CPT code 0191T in assigning the device offset percentage for CPT code 66991 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (*e.g.,* irrigation and aspiration or phacoemulsification); with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more);
- The predecessor CPT code 0191T in assigning the device offset percentage for CPT code 0671T (Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more);
- The predecessor CPT code 0548T in assigning the device offset percentage for CPT code 53451 (Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance);
- The predecessor CPT code 0549T in assigning the device offset percentage for CPT code 53452 (Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance); and
- The predecessor HCPCS code C9752 in assigning the device offset percentage for CPT code 64628 (Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral).

Additionally, at the August 18, 2021 HOP Panel Meeting, a presenter requested that we use the predecessor CPT code 64568 (Incision for implantation of cranial nerve (*e.g.,* vagus nerve) neurostimulator electrode array and pulse generator) in assigning the device offset percentage for CPT code 64582 (Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array). Based on the information presented at the meeting, the HOP Panel recommended we use CPT code 64568 to assign the device offset percentage for CPT code 64582.

Response: We agree with the commenters and the HOP Panel's recommendation. We note that we inadvertently did not apply device offset percentages to the new HCPCS codes mentioned by commenters and recommended by the HOP Panel where claims data of a predecessor code was available. Therefore, we are revising the device offset percentages for these procedures for this final rule to use CY 2019 claims data from these procedures' predecessor codes.

Comment: One commenter requested that we assign HCPCS code C9778 (Colpopexy, vaginal; minimally invasive extra-peritoneal approach (sacrospinous)) device-intensive status as this procedure meets our device-intensive criteria.

Response: After further review, we agree with the commenter that HCPCS code C9778 meets our criteria for device-intensive status. We are accepting the commenter's recommendation and assigning a default device offset percentage of 31 percent to HCPCS code C9778 under the ASC payment system for CY 2022.

Comment: Commenters requested that we assign device-intensive status to:

- CPT code 0499T (Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed);
- CPT code 58674 (Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency);

- CPT code 50590 (Lithotripsy, extracorporeal shock wave);
- CPT code 59200 (Insertion of cervical dilator (*e.g.,* laminaria, prostaglandin) (separate procedure));
- CPT code 66174 (Transluminal dilation of aqueous outflow canal; without retention of device or stent);
- CPT code 66175 (Transluminal dilation of aqueous outflow canal; with retention of device or stent);
- CPT code 93571 (Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (list separately in addition to code for primary procedure); and
- HCPCS code C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar).

Response: Based on CY 2019 claims data available for this final rule, the procedures requested by commenters do not have device offset percentages that exceed the 30-percent threshold required for device-intensive status under the OPPS or ASC payment system and, therefore, are not eligible to be assigned device-intensive status.

Comment: Some commenters recommended that the 30 percent device-intensive threshold be based on the final ASC payment rate and not OPPS costs. Additionally, one commenter requested that we lower the device-intensive threshold to 25 percent.

Response: We do not believe device offset percentages should be determined by dividing the OPPS-derived device offset portion by the final ASC payment rate as this would, in effect, be substantially reducing the device-intensive threshold under the ASC payment system. As we stated in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86015), lowering the device-intensive threshold assigns a greater amount of device costs, which are held constant between the OPPS and ASC payment system, into the prospective year. Lowering the device-intensive threshold, even to 25 percent, would put additional downward pressure on the ASC weight scalar and reduce the nondevice portion of ASC payment rates for surgical procedures. Therefore, for these reasons we are not accepting these recommendations.

Comment: One commenter suggested that we modify the device-intensive criteria to allow packaged procedures that trigger a complexity adjustment under OPPS to be eligible for device-intensive status under the ASC payment system.

Response: We do not believe any changes are warranted to our packaging policies under the ASC payment system at this time. Therefore, we are not accepting this comment but may consider it in future rulemaking.

Comment: One commenter recommended we publish an Addendum to our proposed and final rules that displays the device offset percentages for both device-intensive and nondevice-intensive procedures under the ASC payment system similar to Addendum P for the OPPS.

Response: We are accepting this recommendation. We are creating an Addendum FF for this final rule with comment period and subsequent proposed and final rules that will display the device offset percentages calculated under the standard ASC ratesetting methodology for covered surgical procedures.

After review of the public comments we received, we are finalizing our proposed methodology, without modification, to designate surgical procedures as device-intensive under the ASC payment system. Specifically, for CY 2022 and subsequent years, we are finalizing our proposal to designate procedures as device-intensive procedures if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. Additionally, for CY 2022 and subsequent years, we are finalizing our proposal that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent.

Additionally, after reviewing the public comments we received, we are designating the ASC covered surgical procedures displayed in Addendum AA with payment indicator ''J8'' as device-intensive and subject to the device-intensive procedure payment methodology for CY 2022. The full listing of the final CY 2022 device offset percentages under the ASC payment system for covered surgical procedures can be found in Addendum FF to the CY 2022 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website).

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in § 416.179 of our regulations, and is consistent with the OPPS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices. ASC payment is reduced by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

Effective CY 2014, under the OPPS, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the amount of the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

Under current ASC policy, all ASC device-intensive covered surgical procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS ''FB'' modifier on the line in the claim with the procedure

to implant or insert the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

Effective in CY 2019 (83 FR 59043 through 59044), for partial credit, we adopted a policy to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC will append the HCPCS ''FC'' modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs have the option of either: (1) Submitting the claim for the device-intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our ''FB''/''FC'' modifier policy to all device-intensive procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY 2019 and subsequent calendar years.

Therefore, we proposed to apply our policy for partial credits specified in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) in CY 2022 and subsequent calendar years. Specifically, for CY 2022 and subsequent calendar years, we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device, ASCs have the option of either: (1) Submitting the claim for the device intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount.

We did not receive any comments on our policies related to no/cost full credit or partial credit devices, and we are continuing our existing policies for CY 2022 and subsequent years.

d. Additions to the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can also be safely performed in an ASC, a CAH, or an HOPD, and to review and update the list of ASC procedures at least every 2 years. We evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added to or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders.

From CY 2008 through CY 2020, under our regulations at §§ 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2008, were surgical procedures that met the general standards specified in § 416.166(b) and were not excluded under the general exclusion criteria specified in § 416.166(c). Specifically, under § 416.166(b), the general standards provided that covered surgical procedures were surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that were separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictated that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. Section 416.166(c) set out the general exclusion criteria used under the ASC payment system to evaluate the safety of procedures for performance in an ASC. The general exclusion criteria provided that covered surgical procedures do not include those surgical procedures that: (1) Generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15. For a discussion of the history of our policies for adding surgical procedures to the ASC CPL, we refer readers to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86143 through 86145).

In the CY 2021 OPPS/ASC final rule with comment period, we significantly revised our policy for adding surgical procedures to the ASC CPL. We revised the definition of covered surgical procedures at 42 CFR 416.166(a) and (b) to add new subparagraphs to provide that, for services furnished on or after January 1, 2021, covered surgical procedures for purposes of the ASC CPL are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the

CMS website that: Are separately paid under the OPPS; and are not: Designated as requiring inpatient care as of December 31, 2020; only able to be reported using a CPT unlisted surgical procedure code; or otherwise excluded under § 411.15.

We added a new paragraph (d) to § 416.166 to provide that the general exclusion and general standard criteria that we used to identify covered surgical procedures furnished between January 1, 2008 and December 31, 2020, would, beginning January 1, 2021, be safety factors that physicians consider as to a specific beneficiary when determining whether to perform a covered surgical procedure. We also added a new paragraph (e) to § 416.166 to provide that, on or after January 1, 2021, we add surgical procedures to the list of ASC covered surgical procedures either when we identify a surgical procedure that meets the requirements of paragraph (b)(2) or we are notified of a surgical procedure that could meet the requirements of paragraph (b)(2) and we confirm that such procedure meets those requirements. We added 267 surgical procedures to the ASC CPL that met the revised criteria for covered surgical procedures beginning in CY 2021.

As we explained in the CY 2021 OPPS/ASC final rule with comment period, there were a number of reasons that we made changes to our ASC CPL policy, including that ASCs are increasingly able to safely provide services that meet some of the general exclusion criteria. We explained that we believed it was important that we adapt the ASC CPL in light of significant advances in medical practice, surgical techniques, and ASC capabilities (85 FR 86150). We stated that, while many of the procedures we were adding to the ASC CPL were performed on non-Medicare patients who tend to be younger and have fewer comorbidities than the Medicare population, we believed careful patient selection could identify Medicare beneficiaries who are suitable candidates to receive these services in the ASC setting. We also emphasized the importance of ensuring that the healthcare system has as many access points and patient choices for Medicare beneficiaries as possible, which includes enabling physicians and patients to choose the ASC as the site of care when appropriate. Finally, we reiterated the critical role that physicians play in determining the appropriate site of care for their patients, including whether a surgical procedure can be safely performed in the ASC setting for an individual patient.

1. Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2022

Since the CY 2021 OPPS/ASC final rule was published, we have reexamined our ASC CPL policy and the public comments we received in response to the CY 2021 OPPS/ASC proposed rule, considered the concerns we received from stakeholders since the final rule was published, and conducted an internal clinical review of the 267 procedures we added to the ASC CPL under our revised policy beginning in CY 2021. After examining our revised policy and the feedback we have received, and reviewing the procedures we added to the ASC CPL under our revised policy, we have reconsidered our policy and believe that the policy may not appropriately assess the safety of performing surgical procedures on a typical Medicare beneficiary in an ASC, and that 258 of the 267 surgical procedures we added to the ASC CPL beginning in CY 2021 under our revised policy may not be appropriate to be performed on a typical beneficiary in the ASC setting.

We believe that our current policy—to shift consideration of the general standards and exclusion criteria we have historically used to determine whether a surgical procedure should be added to the ASC CPL from CMS to physicians—needs to be modified to better ensure that surgical procedures added to the ASC CPL under the revised criteria can be performed safely in the ASC setting on the typical Medicare beneficiary. We recognize that appropriate patient selection and physicians' complex medical judgment could help mitigate risks for patient safety. But while we are always striving to balance the goals of increasing physician and patient choice, and expanding site neutral options with patient safety considerations, we nonetheless believe the current policy could be improved with additional patient safety considerations in determining whether a surgical procedure should be added to the ASC CPL.

One issue we identified with our revised policy is that many of the procedures added in CY 2021 would only be appropriate for Medicare beneficiaries who are healthier and have less complex medical conditions than the typical beneficiary. Upon further review, we believe the subset of Medicare beneficiaries who may be suitable candidates to receive these procedures in an ASC setting do not necessarily represent the typical Medicare beneficiary. After evaluating the 267 surgery or surgery-like codes that were added last year, CMS clinicians determined that 258 of these surgical procedures may pose a significant safety risk to a typical Medicare beneficiary when performed in an ASC, including that nearly all would likely require active medical monitoring and care at midnight following the procedure. In the CY 2021 OPPS/ASC final rule with comment period, we established that physicians would consider certain safety factors as to a specific beneficiary when determining whether to perform a covered surgical procedure in an ASC. However, while a physician can make safety determinations for a specific beneficiary, CMS is in the position to make safety determinations for the broader population of Medicare beneficiaries.

While there could be some appropriately selected patient populations for which some of these procedures could be safely performed in the ASC setting, that may not be the case for the typical Medicare beneficiary, due to comorbidities and other health risks that may require more intensive care and monitoring than provided in an ASC setting among this population. We believe it is appropriate to assess the safety of these procedures in the context of the typical Medicare beneficiary, whose health status is representative of the broader Medicare population. Thus, we believe evaluating procedures for their potential to require additional care and monitoring for the typical beneficiary is an appropriate consideration for CMS to make in determining which procedures can safely be performed in an ASC.

We are concerned that, under our current policy, we do not make an active enough determination about whether a procedure is suitable to perform on a typical Medicare beneficiary in an ASC setting. The policy finalized last year allows individual physicians discretion to perform a number of procedures in the ASC setting that would not necessarily be appropriate for the typical Medicare beneficiary in that setting. Clinicians apply appropriate screening criteria to determine either that the procedure should not be performed in the ASC setting because of the risks to the specific beneficiary, or that the specific beneficiary presents a low enough risk profile that the procedure could be safely performed in the ASC setting.

However, we want to reiterate that, in accordance with section 1833(i)(1)(A) of the Act, the Secretary shall specify those surgical procedures that are appropriately (when considered in

terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but that also can be performed safely on an ambulatory basis in an ambulatory surgical center. That is, if Medicare allows payment for these services in the ASC setting, it means that Medicare has determined that the procedure is safe to perform on the typical Medicare beneficiary.

Accordingly, the addition of a procedure to the ASC CPL can signal to physicians that the procedure is safe to perform on the typical Medicare beneficiary in the ASC setting, even though the current criteria, adopted in CY 2021, for adding procedures to the ASC CPL do not include safety criteria other than ensuring that the procedure was not on the IPO list as of CY 2020. We recognize that, while there are similarities between the ASC and HOPD settings, there are also significant differences between the two care settings. The HOPD setting has additional capabilities, resources, and certifications that are not required for the ASC setting. For example, hospitals operate 24/7 and are subject to EMTALA requirements, while ASCs are not. Therefore, a procedure that can be furnished in the HOPD setting is not necessarily safe and appropriate to perform in an ASC setting simply because we make payment for the procedure when it is furnished in the HOPD setting.

In light of these concerns, in the CY 2022 OPPS/ASC proposed rule, we proposed to revise the criteria and process for adding procedures to the ASC CPL by reinstating the ASC CPL policy and regulation text that were in place in CY 2020. While this approach is a departure from the revised policy we adopted for CY 2021, it is consistent with our policy from CY 2008 through CY 2020 where we gradually expanded the ASC CPL while giving careful consideration to safety concerns and risks to the typical beneficiary. This approach would also continue to support our efforts to maximize patient access to care by, when appropriate, adding procedures to the ASC CPL to further increase the availability of ASCs as an alternative, lower cost site of care. While expanding the ASC CPL offers benefits like preserving the capacity of hospitals to treat more acute patients and promoting site neutrality, it is also essential that any expansion of the ASC CPL be done in a carefully calibrated fashion to ensure that Medicare is appropriately signaling that a procedure is safe to be performed in the ASC setting for a typical Medicare beneficiary.

Accordingly, for CY 2022, we proposed to revise the requirements for covered surgical procedures in the regulation at § 416.166 to reinstate the specifications we had established prior to CY 2021. Specifically, we proposed that, effective for services furnished on or after January 1, 2022, covered surgical procedures are those procedures that meet the general standards and do not meet the general exclusions. We proposed to again provide in paragraph (b) of § 416.166 that, subject to the exclusions we proposed to again include in paragraph (c), covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. We proposed to revise paragraph (c) to again include the five criteria currently included in paragraph (d) of the regulation as safety factors physicians consider. We proposed that revised paragraph (c) would provide that, notwithstanding paragraph (b), covered surgical procedures do not include those surgical procedures that: (1) Generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life-threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15. We proposed to remove the physician considerations at § 416.166(d) and change the notification process at § 416.166(e) to a nomination process, which is discussed further in section (d)(2) below.

We stated that we expect that we would continue to expand the ASC CPL in future years under our proposed revised criteria as the practice of medicine and medical technology continue to evolve. We believe that adding appropriate procedures to the ASC CPL that meet the safety criteria that we proposed to reinstate would have beneficial effects for Medicare beneficiaries and healthcare professionals, including increased access, better utilization of existing healthcare resources, and expansion of the capacity of the healthcare system.

Comment: Commenters were largely split on the issue of reinstating the general standards and exclusion criteria at § 416.166 that were in place prior to CY 2021. Many commenters opposed this proposal and recommended that CMS not re-adopt these criteria. These commenters expressed concern at the complete reversal to reinstate the longstanding criteria. Commenters contended that this proposal may substitute administrative criteria for physician clinical judgment, reduce beneficiary choice, and increase costs since the lack of payment for the ASC setting would push these procedures into the higher-cost hospital setting.

However, numerous other commenters supported our proposal to reinstate the general standards and exclusion criteria at § 416.166 that were in place prior to CY 2021 due to patient safety and quality of care concerns. Several commenters urged caution in how CMS modifies criteria and adds procedures to the ASC CPL, as they believe there is not enough information about which procedures are clinically appropriate for the ASC setting. One commenter noted that the general standards and exclusion criteria that were in effect in CY 2020 allowed the ASC CPL to evolve and expand with surgical advancements, while ensuring that procedures that continue to pose significant patient safety risks would only be payable when furnished in the hospital setting.

Several commenters, including providers and professional medical societies, expressed their belief that physicians are best equipped to conduct the clinical evaluation of the safety of procedures and decide whether to perform them on a particular beneficiary in a particular setting.

Response: We thank commenters for their feedback and suggestions. After reviewing the public comments provided, we believe that reinstating the longstanding general standards and exclusion criteria that were in place prior to CY 2021 is the most appropriate way to ensure that procedures that cannot be safely performed on an ambulatory basis for the typical Medicare beneficiary are not added to the ASC CPL and payable under the ASC payment system. The general standards and exclusion criteria identify procedures that typically require overnight stays or require post-operative active medical monitoring and care at midnight following the procedure. When used in conjunction with information from public comments, data from inpatient, outpatient, and

ambulatory sites of service, and medical review, we believe these criteria enable us to make an accurate assessment of whether a procedure can be safely performed in an ASC on the typical Medicare beneficiary. As a result, we are finalizing our proposal to revise the regulatory language at § 416.166 and reinstate the general standards and exclusion criteria in place prior to CY 2021. We will take the additional recommendations suggested by commenters into consideration for future rulemaking.

(1) Comment Solicitation on Procedures That Were Added to the ASC CPL in CY 2021 and Would Not Meet the Proposed Revised CY 2022 Criteria

As stated above, we proposed to remove 258 procedures from the ASC CPL for CY 2022 that were added to the ASC CPL in CY 2021 that we believe do not meet the proposed revised CY 2022 ASC CPL criteria. These procedures were listed in Table 45 of CY 2022 OPPS/ASC proposed rule (86 FR 42210). Based on our internal review of preliminary claims submitted to Medicare, we stated in the proposed rule that we do not believe that ASCs have been furnishing the majority of the 267 procedures finalized in 2021. Because of this, we explained that we believed it is unlikely that ASCs have made practice changes in reliance on the policy we adopted in CY 2021. Therefore, we stated that we do not anticipate that ASCs would be significantly affected by the removal of these 258 procedures from the ASC CPL. We sought input from commenters who believe any of the 258 procedures added to the ASC CPL in CY 2021 meet the proposed revised CY 2022 criteria and, if those revised criteria are finalized, should remain on the ASC CPL for CY 2022. We requested any clinical evidence or literature to support commenters' views that any of these procedures meet the proposed revised CY 2022 criteria and should remain on the ASC CPL for CY 2022.

Comment: Numerous commenters did not support our proposal to remove 258 surgical procedures from the ASC CPL beginning in CY 2022 that had been added to the ASC CPL in CY 2021, but that we proposed would not meet the reinstated general standards and exclusion criteria. These commenters, including several ambulatory surgical center associations, providers, and professional associations, supported retaining all 258 procedures on the ASC CPL and requested that CMS reconsider this proposal. Commenters stated that these procedures are being safely and effectively performed on Medicare beneficiaries in the ASC setting with high levels of patient satisfaction, improved efficiency, and lower cost to both the insurer and the patient. Many noted that CMS's decision to add and then remove hundreds of procedures from the ASC CPL was jarring, as well as lacking in transparency and support from data to justify the decision. Several commenters also noted that access to additional surgical procedures in ASCs during the PHE may be an important and viable option for beneficiaries.

However, many other commenters supported our proposal to remove 258 surgical procedures from the ASC CPL, including hospital associations, professional associations, and device manufacturers. These commenters believed that our proposal, if finalized, would lead to improved patient outcomes and safety with fewer complex procedures being done in the ASC setting. Commenters noted that they believe procedures that would pose a high risk of complications that ASCs are not equipped to handle should remain off the ASC CPL until there is careful consideration of the potential safety risks for beneficiaries and the procedures are determined appropriate to be performed in the ASC setting.

Numerous commenters suggested specific codes or code ranges that they believed should be added to or remain on the ASC CPL. We received 140 surgical procedure recommendations in total, listed in Table 61 below. The majority of these recommendations were not accompanied by any supporting literature or evidence, with some providing only experiential data and simply stating support for CMS paying for the surgical procedures when they are furnished in the ASC setting.

Response: We thank commenters for their input. We assessed the commenters' recommendations to keep 140 surgical procedures on the ASC CPL. The recommendations included 123 codes that were part of the 258 codes proposed for removal, 14 codes that were not on the ASC CPL due to being on the Inpatient Only list or not being surgery-like codes, and 3 codes that have been on the ASC CPL and that we did not propose to remove in CY 2022. We individually assessed each of these 140 procedures, evaluating clinical data on these procedures from multiple sites of services, using literature and experiential data provided in public comments, and ASC claims volume from CY 2021 to determine whether these procedures meet each of the proposed regulatory criteria.

Based on our review of the clinical characteristics of the procedures, claims volume in the ASC setting for CY 2021, and their similarity to other procedures that are currently on the ASC CPL, we believe that six procedures (CPT codes 0499T, 54650, 60512, 69660, 28005, and 27412) out of the 140 procedure recommendations we received can be safely performed for the typical beneficiary in the ASC setting and meet the general standards and exclusion criteria for the ASC CPL that we are reinstating. These codes have few to no inpatient admissions and are largely performed in outpatient settings. We agree with commenters who stated that advancements in clinical practice, less invasive techniques, and patient selection have contributed to allowing these procedures to be safely performed in an ASC setting. Therefore, in this final rule with comment period, we are finalizing keeping each of these six procedures on the ASC CPL. These procedures, listed in Table 60 below, are:

- CPT 0499T (Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed);
- CPT 54650 (Orchiopexy, abdominal approach, for intra-abdominal testis (*e.g.,* fowler-stephens));
- CPT 60512 (Parathyroid autotransplantation (list separately in addition to code for primary procedure));
- CPT 69660 (Stapedectomy or stapedotomy with reestablishment of ossicular continuity, with or without use of foreign material);
- CPT 28005 (Incision, bone cortex (*e.g.,* osteomyelitis or bone abscess), foot), and
- CPT 27412 (Autologous chondrocyte implantation, knee).

Of these six procedures, two of the codes (CPT 69660 and CPT 28005) were already on the ASC CPL prior to CY 2020. One of the codes (CPT 27412) was added in CY 2020, and was determined to meet the general standards and exclusion criteria and was not proposed for removal this year. Three codes (CPT 0499T, CPT 54650, CPT 60512) were added to the ASC CPL under the revised criteria in CY 2021 and proposed for removal this year.

Due to patient safety concerns, for the remaining procedures that we proposed to remove from the ASC CPL but that commenters recommended that we retain on the list, we believe that 255 of 258 codes proposed for removal this year should be removed from the ASC CPL and that the 14 procedures not currently on the ASC CPL not be added because they are on the IPO list or are not surgery-like. In the CY 2022 OPPS/ASC proposed rule, we assessed all 258

codes against the revised criteria and proposed to remove them based upon our determination that they did not meet the criteria we proposed to reinstate. Therefore, for this final rule with comment period, we solely re-reviewed the 140 codes that commenters specifically recommended for review, 123 of which were among the 258 codes proposed for removal from the ASC CPL beginning in CY 2022, one code of which was added in CY 2021 that was not proposed for removal, and 16 of which are new codes, in order to consider the additional information received from public comments to determine whether these codes should remain on or be added to the ASC CPL. We explain below for each anatomical category of the 135 recommended procedures our rationale for not including them on the ASC CPL beginning in CY 2022.

- *35 genitourinary codes*, including laparoscopic ureterolithotomy, nephrectomy, and renal ablation, penis and urethra revision procedures, vaginal repair and removal procedures, and hysterectomy procedures. Many of these procedures have associated inpatient admissions, where the beneficiary requires active medical monitoring and care at midnight following the procedure. Additionally, a number of these procedures would pose a significant safety risk to beneficiaries without post-operative inpatient care.
- *31 musculoskeletal codes*, including total shoulder arthroplasty procedures, incision of hip tendons, amputation through metatarsal, reconstruction of mandibular rami procedures, open treatment of orbital floor blowout fracture procedures, knee arthroscopy meniscal transplantation, and lumbar spine fusion procedures. Although a few of these procedures have some claims volume in the outpatient setting, many of them are also complex procedures with inpatient admissions and multiple post-operative inpatient days, where infections and need for intravenous antibiotics are not uncommon events, indicating that the beneficiary would require active monitoring and care past midnight following the procedure.
- *24 cardiovascular codes*, including procedures like blood vessel lesion repair, implantable defibrillator electrode removal, infected graft excision, arm artery repair, insertion and removal of intravascular vena cava filter, or wireless cardiac stimulator insertion. These procedures are largely performed in inpatient settings and require multiple post-operative inpatient days, indicating that the beneficiary would require active monitoring and care past midnight following the procedure. These procedures also involve major blood vessels, are emergent or life threatening in nature, and require systemic thrombolytic therapy in some cases.
- *10 respiratory codes*, including nasal or sinus endoscopies, laryngoplasties, and windpipe incision. While several of these codes have some outpatient volume, these procedures are largely performed in an inpatient setting. Many of these procedures have associated inpatient admissions and multiple post-operative days, indicating the beneficiary would require active monitoring and care past midnight following the procedure. Additionally, some of these procedures could be emergent or life-threatening in nature.
- *12 gastrointestinal codes*, including paraesophageal hernia repairs, laparoscopic esophagogastric fundoplasty, appendectomy, laparoscopic gastric restrictive procedures, and laparoscopic revision or removal of gastric neurostimulator electrodes. While some of these procedures have outpatient volume, many have inpatient admissions and potential procedure risks (*e.g.* perforation), indicating that the beneficiary would require active monitoring and care past midnight following the procedure. Additionally, these procedures can involve prolonged invasion of body cavities, and be life-threatening or emergent in nature. Additionally, several of these procedures are less commonly done in Medicare patients and more frequently performed in a younger population.
- *13 nervous system codes*, including neck spine disk surgery, laminectomy and laminotomy procedures, spinal cord decompression, spinal lamina removal, spinal disk surgery, and spinal canal catheter implant. These codes have associated inpatient admissions and post-operative days, indicating that the beneficiary would require active monitoring and care past midnight following the procedure. Many of these procedures also pose a significant safety risk to the beneficiary when close post-operative neurosurgical surveillance is not frequently provided.
- *4 endocrine codes* including thyroidectomy and parathyroidectomy procedures. While these procedures have outpatient volume, there are inpatient admissions associated with these procedures, indicating the beneficiary would be expected to stay past midnight following the procedure. Additionally, the intraservice time for these procedures can vary greatly, often becoming a prolonged invasion of body cavities.
- *2 chest and lymphatic codes*, including biopsy or excision of lymph nodes and mediastinoscopy with lymph node biopsy. There are inpatient admissions associated with these procedures, indicating the beneficiary would be expected to stay past midnight following the procedure.
- *1 ear code*, decompression of the internal auditory canal. This procedure is largely performed in the inpatient setting and has associated ICU admissions, indicating the beneficiary would be expected to stay past midnight following the procedure. Additionally, patients often require frequent neurosurgical checks in the post-operative period.
- *1 mastectomy code*, modified radical mastectomy. There are inpatient admissions associated with this procedure, indicating the beneficiary would be expected to stay past midnight following the procedure. Additionally, performing this procedure in an ASC can pose safety risks to the typical beneficiary.
- *2 imaging/study codes*, including esophagus motility study and liver elastography. These codes are not surgical or surgery-like procedures and would not be covered when furnished in an ASC.

Given these considerations, we believe that these 135 codes do not meet the proposed criteria to be included on the ASC CPL due to inpatient admissions, multiple-day stays past midnight, safety risks to the typical beneficiary without active post-operative monitoring, involvement of major blood vessels, or prolonged invasion of a body cavity. We also note that there is insufficient volume data to fully assess concerns about patient safety risks when these procedures are performed in the ASC, with fewer than 25 procedures proposed for removal from ASC CPL having more than 10 claims in the ASC setting during CY 2021.

However, as medical practice continues to evolve, we recognize that there will be additional advancements and improvements that allow these procedures to be safely offered in the ASC setting for the typical Medicare beneficiary. We believe that there is potential for some of the procedures removed this year to be added back to the ASC CPL if there is adequate evidence that these procedures meet our criteria and can be safely performed on the typical Medicare beneficiary in the ASC setting. We encourage stakeholders to continue to submit this information in future rulemaking.

In summary, we added 267 procedures to the ASC CPL in the CY

2021 OPPS/ASC final rule with comment period, based on the revised criteria for the ASC CPL. In the CY 2022 OPPS/ASC proposed rule, we proposed to remove 258 of the 267 procedures, based on our proposed reinstatement of the CY 2020 criteria. We requested comment on whether we should keep any of these procedures on the ASC CPL. During the public comment period, commenters recommended that 140 surgical procedures either remain on or be added to the ASC CPL, including 3 codes that have been on the ASC CPL that we did not propose to remove in CY 2022, 123 codes that were among the 258 we proposed for removal from ASC CPL, and 14 codes that were not on the ASC CPL due to being on the IPO list or not surgery-like.

Therefore, in this CY 2022 OPPS/ASC final rule with comment period, after reviewing those 140 procedure recommendations, we are finalizing retaining six codes that commenters recommended we retain on the ASC CPL, specifically the 3 codes that have been on the ASC CPL that we did not proposed to remove in CY 2022, as well as 3 codes of the 258 codes proposed for removal. Thus, we are removing the remaining 255 of 258 codes proposed for removal. These procedures are listed below in Tables 60, 61, and 62 of this CY 2022 OPPS/ASC final rule with comment period.

Nomination Process Proposal

For CY 2022, we proposed to change the current notification process for adding surgical procedures to the ASC CPL to a nomination process. We proposed that external parties, for example, medical specialty societies or other members of the public, could nominate procedures to be added to the ASC CPL. CMS anticipates that stakeholders, such as specialty societies that specialize in and have a deep understanding of the complexities involved in providing certain procedures, would be able to provide valuable suggestions as to which additional procedures may reasonably and safely be performed in an ASC. While members of the public may already suggest procedures to be added to the ASC CPL through meetings with CMS or through public comments on the proposed rule, we believe it may be beneficial to enable the public, particularly specialty societies who are very familiar with procedures in their specialty, to formally nominate procedures based on the latest evidence available as well as input from their memberships. We proposed to include the nomination process in a new subparagraph (d)(1) of § 416.166. We proposed that the regulation at § 416.166(d)(2) would provide that, if we identify a surgical procedure that meets the requirements at paragraph (a) of this section, including a surgical procedure nominated by an external party under paragraph (d)(1), we will propose to add the surgical procedure to the list of ASC covered surgical procedures in the next available annual rulemaking. Under this proposal, we would propose to add a nominated procedure to the ASC CPL if it meets the proposed general standards for covered surgical procedures at proposed § 416.166(b), and does not meet the general exclusions in proposed § 416.166(c).

Specifically, for the OPPS/ASC rulemaking for a calendar year, we proposed to request stakeholder nominations by March 1 of the year prior to the calendar year for the next applicable rulemaking cycle in order to be included in that rulemaking cycle. For example, stakeholders would need to send in nominations by March 1, 2022, to be considered for the CY 2023 rulemaking cycle and potentially have their nominated procedures added to the ASC CPL effective January 1, 2023. We proposed that we would evaluate procedures nominated by stakeholders based on the applicable statutory and regulatory requirements for ASC covered surgical procedures. We proposed to address nominated procedures beginning in the CY 2023 rulemaking cycle. We proposed to address in rulemaking nominated procedures for which stakeholders have provided sufficient information for us to evaluate the procedure. We proposed to include in the applicable proposed rule, a summary of the justification for proposing to add or not add each nominated procedure, which would allow members of the public to assess and comment on nominated procedures during the public comment period. We proposed that, after reviewing comments provided during the public comment period, we would indicate whether or not we are adding the procedures to ASC CPL in this final rule with comment period. In the event that CMS determines that a nominated procedure does not meet the criteria to be added to the ASC CPL, we would provide our rationale in the rulemaking. We indicated that in certain cases we may need to defer a proposal regarding a nominated procedure to the next regulatory cycle or future rulemaking in order to have sufficient time to evaluate and make an appropriate proposal about the nominated procedure.

We also sought comment on how we might prioritize our review of nominated procedures, in the event we receive an unexpectedly or extraordinarily large volume of nominations for which CMS has insufficient resources to address in the annual rulemaking. For example, if we could not address every nomination in a rulemaking cycle due to a large volume, we may need to prioritize our review such that we would only address in rulemaking those nominations that merit priority. Therefore, we sought comments as to how CMS should prioritize nominations. For example, whether we would prioritize the nominations that have codes nominated by multiple organizations or individuals, codes recently removed from the IPO list, codes accompanied by evidence that other payers are paying for the service on an outpatient basis or in an ASC setting, or a variety of other factors. We stated that, if we were to finalize a prioritization hierarchy for CMS' review of nominated procedures to the ASC CPL, we would indicate in regulation text, likely in proposed § 416.166(d)(2) *Inclusion in Rulemaking:* (1) That CMS would apply a prioritization hierarchy for reviewing nominated procedures if necessary because of an unexpectedly or extraordinarily large volume of nominations; and (2) specify CMS' prioritization hierarchy.

We stated that we believe this nominations proposal allows for the expansion of the ASC CPL in a more gradual fashion, which would better balance the goals of increasing patient choice and expanding site neutral options with patient safety considerations. We stated that we believe a nomination process will take time to develop because we want to incorporate stakeholder input on the most effective way to structure this process. We also acknowledged that stakeholders will need time to consider and evaluate potential surgical procedures to nominate. We proposed to accept nominations for surgical procedures to be added to the ASC CPL beginning in CY 2023.

Comment: The majority of commenters, which included device manufacturers, hospital associations, and ambulatory surgery associations, supported the proposal to establish a process for the public to nominate procedures for addition to the ASC CPL. Stakeholders believed this process would provide more transparency and engagement on procedures earlier in the process, formalize the review process, and allow for more gradual expansion of the ASC CPL. One commenter suggested CMS publish nominations publicly before the proposed rule each year to

allow more opportunity for input, while another requested more information on the data needs related to the nomination process. Two commenters did not support the nomination process as they believe it would cause additional bureaucracy and delay the ASC CPL additions process.

Commenters offered suggestions on different approaches for CMS to consider when approaching criteria including prioritizing procedures endorsed by physician specialty societies, ASC specialty societies, and/or multi-specialty physician organizations that can directly attest to the safety profile of procedures furnished in ASCs; consider real-world evidence when evaluating a procedure for addition to the ASC CPL; consider evidence that commercial payers are paying for a service in the ASC setting for private and/or Medicare Advantage patients; consider procedures that have been successfully performed for Medicare FFS patients during the COVID–19 PHE under the ''Hospital without Walls'' initiative; convene a panel of medical experts to assess the ASC CPL criteria to ensure they reflect contemporary thinking and current medical practice; take into account current length of stay (LOS) requirements of a procedure; determine how procedures promote access for beneficiaries and providing deference to the patient-clinician decision-making process; and develop a framework that combines aspects of cost savings based on site of service, patient safety considerations, and volume of procedures that can and have been performed in an ASC setting.

Response: We thank the commenters for their input on the nomination process. We agree with commenters that a formalized process whereby the public notifies CMS of procedures to be added to the ASC CPL would provide more transparency and increase opportunities for CMS to engage with providers and external stakeholders in adding procedures to the ASC CPL. We intend to provide details on how procedures can be nominated early next year, in order for commenters to be able to send their nominations on March 1, 2022. After consideration of the public comments we received, we are finalizing our proposal to add a nomination process under our current regulations at § 416.166(d)(1), which describes how an external party may nominate a surgical procedure by March 1 of a calendar year for the ASC CPL for the following year. We are also finalizing the regulation text we proposed to add at § 416.166(d)(2), which provides that if CMS identifies a surgical procedure that meets the requirements at § 416.166(a), including a surgical procedure nominated under paragraph (d)(1), it will propose to add the surgical procedure to the ASC CPL in the next available rulemaking.

BILLING CODE 4120–01–P

TABLE 60: SURGICAL PROCEDURES FINALIZED FOR RETENTION ON THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2022

CY 2022 CPT/HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
0499T	Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed	G2
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (e.g., fowler-stephens)	G2
27412	Autologous chondrocyte implantation, knee	J8
60512	Parathyroid autotransplantation (list separately in addition to code for primary procedure)	N1
69660	Stapedectomy or stapedotomy with reestablishment of ossicular continuity, with or without use of foreign material;	A2
28005	Incision, bone cortex (e.g., osteomyelitis or bone abscess), foot	A2

TABLE 61: 140 SURGICAL PROCEDURE RECOMMENDATIONS RECEIVED FROM COMMENTERS

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle	X5
20100	Exploration of penetrating wound (separate procedure); neck	X5
21049	Excision of benign tumor or cyst of maxilla; requiring extra-oral osteotomy and partial maxillectomy (e.g., locally aggressive or destructive lesion[s])	X5
21193	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; without bone graft	X5
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation	X5
21256	Reconstruction of orbit with osteotomies (extracranial) and with bone grafts (includes obtaining autografts) (e.g., micro-ophthalmia)	X5
21346	Open treatment of nasomaxillary complex fracture (lefort ii type); with wiring and/or local fixation	X5
21385	Open treatment of orbital floor blowout fracture; transantral approach (caldwell-luc type operation)	X5
21386	Open treatment of orbital floor blowout fracture; periorbital approach	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
21387	Open treatment of orbital floor blowout fracture; combined approach	X5
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)	X5
21408	Open treatment of fracture of orbit, except blowout; with bone grafting (includes obtaining graft)	X5
21470	Open treatment of complicated mandibular fracture by multiple surgical approaches including internal fixation, interdental fixation, and/or wiring of dentures or splints	X5
22015	Incision and drainage, open, of deep abscess (subfascial), posterior spine; lumbar, sacral, or lumbosacral	X5
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	X5
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar	X5
22850	Removal of posterior nonsegmental instrumentation (e.g., harrington rod)	X5
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty	X5
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (e.g., total shoulder))	X5
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component	X5
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	X5
27005	Tenotomy, hip flexor(s), open (separate procedure)	X5
27006	Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)	X5
27025	Fasciotomy, hip or thigh, any type	X5
27235	Percutaneous skeletal fixation of femoral fracture, proximal end, neck	X5
27412	Autologous chondrocyte implantation, knee	J8
27472	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	X5
27486	Revision of total knee arthroplasty, with or without allograft; 1 component	X5
27535	Open treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed	X5
28005	Incision, bone cortex (e.g., osteomyelitis or bone abscess), foot	A2
28805	Amputation, foot; transmetatarsal	X5
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	X5
31292	Nasal/sinus endoscopy, surgical, with orbital decompression; medial or inferior wall	X5
31293	Nasal/sinus endoscopy, surgical, with orbital decompression; medial and inferior wall	X5
31294	Nasal/sinus endoscopy, surgical, with optic nerve decompression	X5
31584	Laryngoplasty; with open reduction and fixation of (e.g., plating) fracture, includes tracheostomy, if performed	X5
31587	Laryngoplasty, cricoid split, without graft placement	X5
31600	Tracheostomy, planned (separate procedure);	X5
31601	Tracheostomy, planned (separate procedure); younger than 2 years	X5
31610	Tracheostomy, fenestration procedure with skin flaps	X5
32551	Tube thoracostomy, includes connection to drainage system (e.g., water seal), when performed, open (separate procedure)	X5
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction	X5
35045	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery	X5
35201	Repair blood vessel, direct; neck	X5
35206	Repair blood vessel, direct; upper extremity	X5
35231	Repair blood vessel with vein graft; neck	X5
35236	Repair blood vessel with vein graft; upper extremity	X5
35261	Repair blood vessel with graft other than vein; neck	X5
35903	Excision of infected graft; extremity	X5
37191	Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	X5
37193	Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	X5
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)	X5
39402	Mediastinoscopy; with lymph node biopsy(ies) (e.g., lung cancer staging)	X5
43280	Laparoscopy, surgical, esophagogastric fundoplasty (e.g., nissen, toupet procedures)	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	X5
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh	X5
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum	X5
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum	X5
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)	X5
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only	X5
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only	X5
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components	X5
44180	Laparoscopy, surgical, enterolysis (freeing of intestinal adhesion) (separate procedure)	X5
44950	Appendectomy;	X5
44970	Laparoscopy, surgical, appendectomy	X5
50020	Drainage of perirenal or renal abscess, open	X5
50541	Laparoscopy, surgical; ablation of renal cysts	X5
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed	X5
50543	Laparoscopy, surgical; partial nephrectomy	X5
50544	Laparoscopy, surgical; pyeloplasty	X5
50945	Laparoscopy, surgical; ureterolithotomy	X5
51060	Transvesical ureterolithotomy	X5
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (e.g., stamey, raz, modified pereyra)	X5
51860	Cystorrhaphy, suture of bladder wound, injury or rupture; simple	X5
51990	Laparoscopy, surgical; urethral suspension for stress incontinence	X5
53500	Urethrolysis, transvaginal, secondary, open, including cystourethroscopy (e.g., postsurgical obstruction, scarring)	X5
54332	1-stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
54336	1-stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	X5
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	X5
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	X5
54535	Orchiectomy, radical, for tumor; with abdominal exploration	X5
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (e.g., fowler-stephens)	G2
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	X5
55970	Intersex surgery; male to female	X5
55980	Intersex surgery; female to male	X5
57106	Vaginectomy, partial removal of vaginal wall;	X5
57107	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy)	X5
57109	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy) with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy)	X5
57284	Paravaginal defect repair (including repair of cystocele, if performed); open abdominal approach	X5
57285	Paravaginal defect repair (including repair of cystocele, if performed); vaginal approach	X5
57292	Construction of artificial vagina; with graft	X5
57330	Closure of vesicovaginal fistula; transvesical and vaginal approach	X5
57335	Vaginoplasty for intersex state	X5
57423	Paravaginal defect repair (including repair of cystocele, if performed), laparoscopic approach	X5
57555	Excision of cervical stump, vaginal approach; with anterior and/or posterior repair	X5
58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele	X5
58290	Vaginal hysterectomy, for uterus greater than 250 g;	X5
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	X5
58292	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
58294	Vaginal hysterectomy, for uterus greater than 250 g; with repair of enterocele	X5
58925	Ovarian cystectomy, unilateral or bilateral	X5
60252	Thyroidectomy, total or subtotal for malignancy; with limited neck dissection	X5
60260	Thyroidectomy, removal of all remaining thyroid tissue following previous removal of a portion of thyroid	X5
60271	Thyroidectomy, including substernal thyroid; cervical approach	X5
60502	Parathyroidectomy or exploration of parathyroid(s); re-exploration	X5
60512	Parathyroid autotransplantation (list separately in addition to code for primary procedure)	N1
62351	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; with laminectomy	X5
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; sacral	X5
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (gill type procedure)	X5
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; cervical	X5
63016	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; thoracic	X5
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; lumbar	X5
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (list separately in addition to code for primary procedure)	X5
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
63043	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (list separately in addition to code for primary procedure)	X5
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (list separately in addition to code for primary procedure)	X5
63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (list separately in addition to code for primary procedure)	X5
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace	X5
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (list separately in addition to code for primary procedure)	X5
69660	Stapedectomy or stapedotomy with reestablishment of ossicular continuity, with or without use of foreign material;	A2
69960	Decompression internal auditory canal	X5
91010	Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report;	S1
91200	Liver elastography, mechanically induced shear wave (e.g., vibration), without imaging, with interpretation and report	N1
0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar	X5
0499T	Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed	G2
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
0515T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])	X5
0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only	X5
0517T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; pulse generator component(s) (battery and/or transmitter) only	X5
0518T	Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing	X5
0519T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)	X5
0520T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter), including placement of a new electrode	X5
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	X5
C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	X5
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	X5
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	X5
C9606	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy	C5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
	and angioplasty, including aspiration thrombectomy when performed, single vessel	
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel	X5
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	X5

TABLE 62: 255 SURGICAL PROCEDURES FINALIZED FOR REMOVAL FROM THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2022

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle	X5
20100	Exploration of penetrating wound (separate procedure); neck	X5
20101	Exploration of penetrating wound (separate procedure); chest	X5
20102	Exploration of penetrating wound (separate procedure); abdomen/flank/back	X5
20660	Application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure)	X5
21049	Excision of benign tumor or cyst of maxilla; requiring extra-oral osteotomy and partial maxillectomy (e.g., locally aggressive or destructive lesion[s])	X5
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)	X5
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (e.g., plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)	X5
21193	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; without bone graft	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation	X5
21256	Reconstruction of orbit with osteotomies (extracranial) and with bone grafts (includes obtaining autografts) (e.g., micro-ophthalmia)	X5
21261	Periorbital osteotomies for orbital hypertelorism, with bone grafts; combined intra- and extracranial approach	X5
21263	Periorbital osteotomies for orbital hypertelorism, with bone grafts; with forehead advancement	X5
21346	Open treatment of nasomaxillary complex fracture (lefort ii type); with wiring and/or local fixation	X5
21385	Open treatment of orbital floor blowout fracture; transantral approach (caldwell-luc type operation)	X5
21386	Open treatment of orbital floor blowout fracture; periorbital approach	X5
21387	Open treatment of orbital floor blowout fracture; combined approach	X5
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)	X5
21408	Open treatment of fracture of orbit, except blowout; with bone grafting (includes obtaining graft)	X5
21470	Open treatment of complicated mandibular fracture by multiple surgical approaches including internal fixation, interdental fixation, and/or wiring of dentures or splints	X5
21601	Excision of chest wall tumor including rib(s)	X5
21742	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (nuss procedure), without thoracoscopy	X5
21743	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (nuss procedure), with thoracoscopy	X5
22100	Partial excision of posterior vertebral component (e.g., spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; cervical	X5
22101	Partial excision of posterior vertebral component (e.g., spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; thoracic	X5
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty	X5
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component	X5
24150	Radical resection of tumor, shaft or distal humerus	X5
24935	Stump elongation, upper extremity	X5
25170	Radical resection of tumor, radius or ulna	X5
25909	Amputation, forearm, through radius and ulna; re-amputation	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
27006	Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)	X5
27027	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (e.g., gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle), unilateral	X5
27057	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (e.g., gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle) with debridement of nonviable muscle, unilateral	X5
27179	Open treatment of slipped femoral epiphysis; osteoplasty of femoral neck (heyman type procedure)	X5
27235	Percutaneous skeletal fixation of femoral fracture, proximal end, neck	X5
27477	Arrest, epiphyseal, any method (e.g., epiphysiodesis); tibia and fibula, proximal	X5
27485	Arrest, hemiepiphyseal, distal femur or proximal tibia or fibula (e.g., genu varus or valgus)	X5
27722	Repair of nonunion or malunion, tibia; with sliding graft	X5
28360	Reconstruction, cleft foot	X5
28805	Amputation, foot; transmetatarsal	X5
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral	X5
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	X5
31292	Nasal/sinus endoscopy, surgical, with orbital decompression; medial or inferior wall	X5
31293	Nasal/sinus endoscopy, surgical, with orbital decompression; medial and inferior wall	X5
31294	Nasal/sinus endoscopy, surgical, with optic nerve decompression	X5
31584	Laryngoplasty; with open reduction and fixation of (e.g., plating) fracture, includes tracheostomy, if performed	X5
31587	Laryngoplasty, cricoid split, without graft placement	X5
31600	Tracheostomy, planned (separate procedure);	X5
31601	Tracheostomy, planned (separate procedure); younger than 2 years	X5
31610	Tracheostomy, fenestration procedure with skin flaps	X5
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	X5
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	X5
31785	Excision of tracheal tumor or carcinoma; cervical	X5
32551	Tube thoracostomy, includes connection to drainage system (e.g., water seal), when performed, open (separate procedure)	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
32560	Instillation, via chest tube/catheter, agent for pleurodesis (e.g., talc for recurrent or persistent pneumothorax)	X5
32561	Instillation(s), via chest tube/catheter, agent for fibrinolysis (e.g., fibrinolytic agent for break-up of multiloculated effusion); initial day	X5
32562	Instillation(s), via chest tube/catheter, agent for fibrinolysis (e.g., fibrinolytic agent for break-up of multiloculated effusion); subsequent day	X5
32601	Thoracoscopy, diagnostic (separate procedure); lungs, pericardial sac, mediastinal or pleural space, without biopsy	X5
32604	Thoracoscopy, diagnostic (separate procedure); pericardial sac, with biopsy	X5
32606	Thoracoscopy, diagnostic (separate procedure); mediastinal space, with biopsy	X5
32607	Thoracoscopy; with diagnostic biopsy(ies) of lung infiltrate(s) (e.g., wedge, incisional), unilateral	X5
32608	Thoracoscopy; with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (e.g., wedge, incisional), unilateral	X5
32609	Thoracoscopy; with biopsy(ies) of pleura	X5
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction	X5
33272	Removal of subcutaneous implantable defibrillator electrode	X5
34101	Embolectomy or thrombectomy, with or without catheter; axillary, brachial, innominate, subclavian artery, by arm incision	X5
34111	Embolectomy or thrombectomy, with or without catheter; radial or ulnar artery, by arm incision	X5
34201	Embolectomy or thrombectomy, with or without catheter; femoropopliteal, aortoiliac artery, by leg incision	X5
34203	Embolectomy or thrombectomy, with or without catheter; popliteal-tibio-peroneal artery, by leg incision	X5
34421	Thrombectomy, direct or with catheter; vena cava, iliac, femoropopliteal vein, by leg incision	X5
34471	Thrombectomy, direct or with catheter; subclavian vein, by neck incision	X5
34501	Valvuloplasty, femoral vein	X5
34510	Venous valve transposition, any vein donor	X5
34520	Cross-over vein graft to venous system	X5
34530	Saphenopopliteal vein anastomosis	X5
35011	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm and associated occlusive disease, axillary-brachial artery, by arm incision	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
35045	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery	X5
35180	Repair, congenital arteriovenous fistula; head and neck	X5
35184	Repair, congenital arteriovenous fistula; extremities	X5
35190	Repair, acquired or traumatic arteriovenous fistula; extremities	X5
35201	Repair blood vessel, direct; neck	X5
35206	Repair blood vessel, direct; upper extremity	X5
35226	Repair blood vessel, direct; lower extremity	X5
35231	Repair blood vessel with vein graft; neck	X5
35236	Repair blood vessel with vein graft; upper extremity	X5
35256	Repair blood vessel with vein graft; lower extremity	X5
35261	Repair blood vessel with graft other than vein; neck	X5
35266	Repair blood vessel with graft other than vein; upper extremity	X5
35286	Repair blood vessel with graft other than vein; lower extremity	X5
35321	Thromboendarterectomy, including patch graft, if performed; axillary-brachial	X5
35860	Exploration for postoperative hemorrhage, thrombosis or infection; extremity	X5
35879	Revision, lower extremity arterial bypass, without thrombectomy, open; with vein patch angioplasty	X5
35881	Revision, lower extremity arterial bypass, without thrombectomy, open; with segmental vein interposition	X5
35883	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with nonautogenous patch graft (e.g., dacron, eptfe, bovine pericardium)	X5
35884	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with autogenous vein patch graft	X5
35903	Excision of infected graft; extremity	X5
36460	Transfusion, intrauterine, fetal	X5
36838	Distal revascularization and interval ligation (dril), upper extremity hemodialysis access (steal syndrome)	X5
37183	Revision of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract recannulization/dilatation, stent placement and all associated imaging guidance and documentation)	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
37191	Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	X5
37192	Repositioning of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	X5
37193	Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	X5
37195	Thrombolysis, cerebral, by intravenous infusion	X5
37213	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed;	X5
37214	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed; cessation of thrombolysis including removal of catheter and vessel closure by any method	X5
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation	X5
37565	Ligation, internal jugular vein	X5
37600	Ligation; external carotid artery	X5
37605	Ligation; internal or common carotid artery	X5
37606	Ligation; internal or common carotid artery, with gradual occlusion, as with selverstone or crutchfield clamp	X5
37615	Ligation, major artery (e.g., post-traumatic, rupture); neck	X5
37619	Ligation of inferior vena cava	X5
38120	Laparoscopy, surgical, splenectomy	X5
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor	X5
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor	X5
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, t-cell depletion	X5
38211	Transplant preparation of hematopoietic progenitor cells; tumor cell depletion	X5
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal	X5
38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion	X5
38214	Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion	X5
38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer	X5
38240	Hematopoietic progenitor cell (hpc); allogeneic transplantation per donor	X5
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)	X5
38720	Cervical lymphadenectomy (complete)	X5
39401	Mediastinoscopy; includes biopsy(ies) of mediastinal mass (e.g., lymphoma), when performed	X5
39402	Mediastinoscopy; with lymph node biopsy(ies) (e.g., lung cancer staging)	X5
42842	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; without closure	X5
42844	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; closure with local flap (e.g., tongue, buccal)	X5
43020	Esophagotomy, cervical approach, with removal of foreign body	X5
43280	Laparoscopy, surgical, esophagogastric fundoplasty (e.g., nissen, toupet procedures)	X5
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	X5
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh	X5
43420	Closure of esophagostomy or fistula; cervical approach	X5
43510	Gastrotomy; with esophageal dilation and insertion of permanent intraluminal tube (e.g., celestin or mousseaux-barbin)	X5
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum	X5
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum	X5
43651	Laparoscopy, surgical; transection of vagus nerves, truncal	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
43652	Laparoscopy, surgical; transection of vagus nerves, selective or highly selective	X5
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)	X5
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only	X5
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only	X5
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components	X5
43830	Gastrostomy, open; without construction of gastric tube (e.g., stamm procedure) (separate procedure)	X5
43831	Gastrostomy, open; neonatal, for feeding	X5
44180	Laparoscopy, surgical, enterolysis (freeing of intestinal adhesion) (separate procedure)	X5
44186	Laparoscopy, surgical; jejunostomy (e.g., for decompression or feeding)	X5
44950	Appendectomy;	X5
44955	Appendectomy; when done for indicated purpose at time of other major procedure (not as separate procedure) (list separately in addition to code for primary procedure)	X5
44970	Laparoscopy, surgical, appendectomy	X5
47370	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); radiofrequency	X5
47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical	X5
47490	Cholecystostomy, percutaneous, complete procedure, including imaging guidance, catheter placement, cholecystogram when performed, and radiological supervision and interpretation	X5
49185	Sclerotherapy of a fluid collection (e.g., lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s), diagnostic study, imaging guidance (e.g., ultrasound, fluoroscopy) and radiological supervision and interpretation when performed	X5
49323	Laparoscopy, surgical; with drainage of lymphocele to peritoneal cavity	X5
49405	Image-guided fluid collection drainage by catheter (e.g., abscess, hematoma, seroma, lymphocele, cyst); visceral (e.g., kidney, liver, spleen, lung/mediastinum), percutaneous	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
49491	Repair, initial inguinal hernia, preterm infant (younger than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; reducible	X5
49492	Repair, initial inguinal hernia, preterm infant (younger than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; incarcerated or strangulated	X5
50020	Drainage of perirenal or renal abscess, open	X5
50541	Laparoscopy, surgical; ablation of renal cysts	X5
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed	X5
50543	Laparoscopy, surgical; partial nephrectomy	X5
50544	Laparoscopy, surgical; pyeloplasty	X5
50945	Laparoscopy, surgical; ureterolithotomy	X5
51060	Transvesical ureterolithotomy	X5
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (e.g., stamey, raz, modified pereyra)	X5
51860	Cystorrhaphy, suture of bladder wound, injury or rupture; simple	X5
51990	Laparoscopy, surgical; urethral suspension for stress incontinence	X5
53500	Urethrolysis, transvaginal, secondary, open, including cystourethroscopy (e.g., postsurgical obstruction, scarring)	X5
54332	1-stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	X5
54336	1-stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	X5
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	X5
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	X5
54535	Orchiectomy, radical, for tumor; with abdominal exploration	X5
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	X5
55970	Intersex surgery; male to female	X5
55980	Intersex surgery; female to male	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
57106	Vaginectomy, partial removal of vaginal wall;	X5
57107	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy)	X5
57109	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy) with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy)	X5
57284	Paravaginal defect repair (including repair of cystocele, if performed); open abdominal approach	X5
57285	Paravaginal defect repair (including repair of cystocele, if performed); vaginal approach	X5
57292	Construction of artificial vagina; with graft	X5
57330	Closure of vesicovaginal fistula; transvesical and vaginal approach	X5
57335	Vaginoplasty for intersex state	X5
57423	Paravaginal defect repair (including repair of cystocele, if performed), laparoscopic approach	X5
57555	Excision of cervical stump, vaginal approach; with anterior and/or posterior repair	X5
58263	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele	X5
58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele	X5
58290	Vaginal hysterectomy, for uterus greater than 250 g;	X5
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	X5
58292	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele	X5
58294	Vaginal hysterectomy, for uterus greater than 250 g; with repair of enterocele	X5
58770	Salpingostomy (salpingoneostomy)	X5
58920	Wedge resection or bisection of ovary, unilateral or bilateral	X5
58925	Ovarian cystectomy, unilateral or bilateral	X5
59030	Fetal scalp blood sampling	X5
59409	Vaginal delivery only (with or without episiotomy and/or forceps);	X5
59612	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps);	X5
60252	Thyroidectomy, total or subtotal for malignancy; with limited neck dissection	X5
60260	Thyroidectomy, removal of all remaining thyroid tissue following previous removal of a portion of thyroid	X5
60271	Thyroidectomy, including substernal thyroid; cervical approach	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
60502	Parathyroidectomy or exploration of parathyroid(s); re-exploration	X5
60520	Thymectomy, partial or total; transcervical approach (separate procedure)	X5
61623	Endovascular temporary balloon arterial occlusion, head or neck (extracranial/intracranial) including selective catheterization of vessel to be occluded, positioning and inflation of occlusion balloon, concomitant neurological monitoring, and radiologic supervision and interpretation of all angiography required for balloon occlusion and to exclude vascular injury post occlusion	X5
61626	Transcatheter permanent occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; non-central nervous system, head or neck (extracranial, brachiocephalic branch)	X5
61720	Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus	X5
62000	Elevation of depressed skull fracture; simple, extradural	X5
62351	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; with laminectomy	X5
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; sacral	X5
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (gill type procedure)	X5
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; cervical	X5
63016	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; thoracic	X5
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; lumbar	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (list separately in addition to code for primary procedure)	X5
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical	X5
63043	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (list separately in addition to code for primary procedure)	X5
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (list separately in addition to code for primary procedure)	X5
63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (list separately in addition to code for primary procedure)	X5
63064	Costovertebral approach with decompression of spinal cord or nerve root(s) (e.g., herniated intervertebral disc), thoracic; single segment	X5
63066	Costovertebral approach with decompression of spinal cord or nerve root(s) (e.g., herniated intervertebral disc), thoracic; each additional segment (list separately in addition to code for primary procedure)	X5
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace	X5
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (list separately in addition to code for primary procedure)	X5
63741	Creation of shunt, lumbar, subarachnoid-peritoneal, -pleural, or other; percutaneous, not requiring laminectomy	X5
64804	Sympathectomy, cervicothoracic	X5
64911	Nerve repair; with autogenous vein graft (includes harvest of vein graft), each nerve	X5
69725	Decompression facial nerve, intratemporal; including medial to geniculate ganglion	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
69955	Total facial nerve decompression and/or repair (may include graft)	X5
69960	Decompression internal auditory canal	X5
69970	Removal of tumor, temporal bone	X5
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	X5
C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	X5
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	X5
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	X5
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel	X5
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	X5
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-d rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
C9758	Blinded procedure for nyha class iii/iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	X5
0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (i.e., tems), including muscularis propria (i.e., full thickness)	X5
0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar	X5
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	X5
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (egj), with implantation of pulse generator, includes programming	X5
0453T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; mechano-electrical skin interface	D5
0454T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; subcutaneous electrode	D5
0457T	Removal of permanently implantable aortic counterpulsation ventricular assist system; mechano-electrical skin interface	D5
0458T	Removal of permanently implantable aortic counterpulsation ventricular assist system; subcutaneous electrode	D5
0460T	Repositioning of previously implanted aortic counterpulsation ventricular assist device; subcutaneous electrode	D5
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	X5
0515T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])	X5

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator
0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only	X5
0517T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; pulse generator component(s) (battery and/or transmitter) only	X5
0518T	Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing	X5
0519T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)	X5
0520T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter), including placement of a new electrode	X5

BILLING CODE 4120–01–C

2. Covered Ancillary Services

In the CY 2019 OPPS/ASC final rule (83 FR 59062 through 59063), consistent with the established ASC payment system policy (72 FR 42497), we finalized the policy to update the ASC list of covered ancillary services to reflect the payment status for the services under the CY 2019 OPPS/ASC final rule with comment period. As discussed in prior rulemaking, maintaining consistency with the OPPS may result in changes to ASC payment indicators for some covered ancillary services because of changes that are being finalized under the OPPS for CY 2022. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2021, but will be packaged under the CY 2022 OPPS, to maintain consistency with the OPPS, we would also package the ancillary service under the ASC payment system for CY 2022. In the CY 2019 OPPS/ASC final rule, we finalized the policy to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator ''CH'', which was discussed in section XIII.F. of the CY 2022 OPPS/ASC proposed rule, is used in Addendum BB to this CY 2022 OPPS/ASC final rule (which is available via the internet on the CMS website) to indicate covered ancillary services for which we are finalizing a change in the ASC payment indicator to reflect a finalized change in the OPPS treatment of the service for CY 2022.

For CY 2022, as discussed in section II.A.3.b. of this final rule with comment period, we are finalizing our proposal to revise 42 CFR 416.164(b)(6) to include, as ancillary items that are integral to a covered surgical procedure and for which separate payment is allowed, non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS in proposed new § 416.174.

New CPT and HCPCS codes for covered ancillary services and their final payment indicators for CY 2022 can be found in section XIII.B of this final rule with comment period. All ASC covered ancillary services and their final payment indicators for CY 2022 are also included in Addendum BB to the CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

D. Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services

1. ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2''. Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator ''A2'' because it is used to identify procedures that are exempted from the application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so only the service portion of the rate is subject to the ASC conversion factor. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86122 through 86179), we updated the CY 2020 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2'', ''G2'', and ''J8'' using CY 2019

data, consistent with the CY 2021 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2021 OPPS device offset percentages calculated under the standard APC ratesetting methodology, as discussed earlier in this section.

Payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') are the lower of the PFS nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting methodology for the procedure. In the CY 2021 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated CY 2021 rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the PFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2021 payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators ''Q1'' and ''Q2'') describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator ''N1'') under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There would be no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal—conditionally packaged in the OPPS (status indicator ''Q2'')—we continued to provide separate payment since CY 2014 and assigned the current ASC payment indicators associated with these procedures.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2022

We proposed to update ASC payment rates for CY 2022 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XII.C.1.b. of the CY 2022 OPPS/ASC proposed rule. Because the proposed OPPS relative payment weights are generally based on geometric mean costs, we proposed that the ASC payment system would generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology. We proposed to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2''.

We proposed to calculate payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') and device-intensive procedures (payment indicator ''J8'') according to our established policies and to use our proposed modified definition to identify device-intensive procedures, as discussed in section XII.C.1.b. of the CY 2022 OPPS/ASC proposed rule. Therefore, we proposed to update the payment amount for the service portion of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed CY 2022 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. We proposed that payment for office-based procedures would be at the lesser of the proposed CY 2022 MPFS nonfacility PE RVU-based amount or the proposed CY 2022 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2021, for CY 2022 we proposed to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2'') would be assigned the current ASC payment indicators associated with those procedures and would continue to be paid separately under the ASC payment system.

Comment: Several commenters recommended that Medicare allow ASCs to bill procedures with an unlisted code, particularly new technologies and innovative techniques in the ASC setting. They noted that many new procedures are performed in the ASC setting before procedure-specific CPT codes are established. These commenters also mentioned that codes include the narrowly defined anatomic region of the service, which could provide the basis for a safety determination, and noted there is not a clear safety rationale for the policy on unlisted codes in the ASC setting. Another commenter requested that MACs be able to price unlisted codes. Commenters requested that CMS eliminate the restriction on billing with unlisted codes in the ASC setting.

Response: Under § 416.166(c)(7), covered surgical procedures do not include procedures that can only be reported using a CPT unlisted surgical procedure code. As discussed in the August 2, 2007 ASC final rule (72 FR 42485), it is not possible to know what specific procedure would be represented by an unlisted code. Additionally, although the code may include the narrowly defined anatomic region of the service, this information is not sufficient to fully assess the procedure against the applicable regulatory criteria at § 416.166. Therefore, as it is not possible to appropriately evaluate procedures reported by unlisted CPT codes, we are not accepting this recommendation.

We are finalizing our proposed policies without modification to calculate the CY 2022 payment rates for ASC covered surgical procedures according to our established rate calculation methodologies under § 416.171 and using the modified definition of device-intensive procedures as discussed in section XIII.C.1.b. of this CY 2022 OPPS/ASC final rule with comment period. For covered office-based surgical procedures, the payment rate is the lower of the final CY 2022 MPFS nonfacility PE RVU-based amount or the final CY 2022 ASC payment amount calculated according to the ASC standard ratesetting methodology. The final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the PFS PE RVUs and the conversion factor effective January 1, 2022. For a discussion of the PFS rates, we refer readers to the CY 2022 PFS final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

c. Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

As stated in section XIII.D.1.b. of the CY 2022 OPPS/ASC proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology. However, for low-volume device-intensive procedures, the proposed relative payment weights are based on median costs, rather than geometric mean costs, as discussed in section IV.B.5. of the CY 2022 OPPS/ASC proposed rule.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61400), we finalized our policy to limit the ASC payment rate for low-volume device-intensive procedures to a payment rate equal to the OPPS payment rate for that procedure. Under this policy, where the ASC payment rate based on the standard ASC ratesetting methodology for low volume device-intensive procedures would exceed the rate paid under the OPPS for the same procedure, we establish an ASC payment rate for such procedures equal to the OPPS payment rate for the same procedure.

As discussed in section X.C of the CY 2022 OPPS/ASC proposed rule (86 FR 42181 through 42185), we proposed a low volume APC policy for CY 2022 and subsequent calendar years. Under our proposal, we expanded the low volume adjustment policy that is applied to procedures assigned to New Technology APCs and applied such policy to clinical and brachytherapy APCs. Specifically, a clinical APC or brachytherapy APC with fewer than 100 claims per year would be designated as a low volume APC. For items and services assigned to APCs we proposed to designate as low volume APCs as well as procedures assigned to New Technology APCs with fewer than 100 claims, we proposed to use up to four years of claims data to establish a payment rate for each item or service as we currently do for low volume services assigned to New Technology APCs. The payment rate for a low volume APC or a low volume New Technology procedure would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data. Because we proposed to adopt a low volume APC policy, we also proposed to eliminate our low volume device-intensive procedure policy and address ratesetting for HCPCS code 0308T—the only code designated as a low volume device-intensive procedure—within our broader low volume APC proposal. Consequently, we proposed to modify our existing regulations at § 416.171(b)(4) to apply our ASC payment rate limitation to services assigned to low volume APCs rather than low volume device-intensive procedures.

We sought comments on our proposal to modify our existing regulations at § 416.171(b)(4) and limit the ASC payment rate for services assigned to low volume APCs to the payment rate for the OPPS.

Comment: One commenter recommended that we not finalize our proposal to apply a limit to the ASC payment rate for services assigned to low volume APCs to the payment rate for the OPPS. The commenter argued that only comprehensive APCs would be affected by our proposal and that the comprehensive ratesetting methodology generally is able to utilize a greater number of claims than under the ASC standard ratesetting methodology. The commenter stated that such additional claims may include claims that are inaccurately coded for other services and thus produce less accurate payment rates.

Response: We disagree. We do not believe ASCs incur greater costs than hospitals and that the ASC payment rate should be greater than the payment rate under the OPPS. We believe such situations represent a data anomaly and that the ASC payment rate should be limited to the OPPS payment rate for procedures assigned to low volume APCs.

After reviewing the public comment we received, we are finalizing our proposal, without modification, to modify our existing regulations at § 416.171(b)(4) and limit the ASC payment rate for services assigned to low volume APCs to the payment rate for the OPPS.

d. Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests

Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116–260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. The reduced coinsurance will be phased-in beginning January 1, 2022. Detailed discussions on implementing this legislation are included in the CY 2022 PFS final rule and section X.B., ''Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests'' of this final rule with comment period.

After considering public comments, we are finalizing the proposals made in the CY 2022 OPPS/ASC proposed rule to implement section 122 of the CAA without modification. Specifically, we are finalizing that all surgical services furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy would be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test for purposes of determining the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter. Providers must continue to report HCPCS modifier ''PT'' to indicate that a planned colorectal cancer screening service converted to a diagnostic service. We will examine the claims data, monitor for any increases in surgical services unrelated to the colorectal cancer screening test performed on the same date as the screening test, and consider revising our policy through rulemaking if there is a notable increase or abuse of this policy.

2. Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N'', ''Q1'', and ''Q2'') under the OPPS. In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment for procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged procedure describes a HCPCS code where the

payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor ''N1'') under the ASC payment system (except for device removal procedures, as discussed in section IV. of the CY 2022 OPPS/ASC proposed rule). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for ancillary items and services also to be paid, the ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in section XIII.D.3. of the CY 2022 OPPS/ASC proposed rule, for CY 2022, we proposed a policy to unpackage and pay separately at ASP plus 6 percent for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under proposed new § 416.174. We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount (''Z3''), regardless of which is lower (§ 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (§ 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a ''device offset'' to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' and revised the definition of payment indicator ''Z2'' to include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3,'' and revised the definition of payment indicator ''Z3'' to include a reference to diagnostic services.

Comment: One commenter recommended that we publish guidance on how MACs are to calculate transitional pass-through payments under the ASC payment system for devices that are eligible for pass-through payment under the OPPS similar to how such guidance is provided under the OPPS.

Response: As previously discussed, devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Transitional pass-through payments under the OPPS utilize hospital cost-to-charge ratios to reduce the pass-through device to cost and provide the hospital an additional payment of the amount by which the cost of the pass-through device exceeds the applicable device offset amount. ASCs do not submit cost reports and, as such, we are unable to replicate the transitional pass-through payment under the ASC payment system. Currently, MACs have been instructed to pay for such devices in the ASC setting based on invoice or cost. We are unaware of a compelling reason, at this time, to provide additional guidance or clarification on this process, beyond that provided in Section 40, Chapter 14 of the Medicare Claims Processing Manual.

b. Final Payment for Covered Ancillary Services for CY 2022

We are finalizing our proposal to update the ASC payment rates and to make changes to ASC payment

indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the final CY 2022 OPPS and ASC payment rates and subsequent year's payment rates. We are also finalizing our proposal to continue to set the CY 2022 ASC payment rates and subsequent year's payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2022 and subsequent year's payment rates.

Covered ancillary services and their final payment indicators for CY 2022 are listed in Addendum BB of this final rule with comment period (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS final rates (similar to our office-based payment policy), the final payment indicators and rates set forth in the final rule are based on a comparison using the proposed PFS rates effective January 1, 2022. For a discussion of the PFS rates, we refer readers to the CY 2022 PFS final rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

3. CY 2022 ASC Packaging Policy for Non-Opioid Pain Management Drugs and Biologicals

Please refer to Section II.A.3.b for a discussion of the final CY 2022 OPPS/ASC for payment for non-opioid pain management drugs and biologicals.

E. New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195.

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

- Applicants submit their NTIOL requests for review to CMS by the annual deadline. For a request to be considered complete, we require submission of the information requested in the guidance document titled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an Existing NTIOL Class'' posted on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*.
- We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.
- In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments.

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2022

We did not receive any requests for review to establish a new NTIOL class for CY 2022 by March 1, 2021, the due date published in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86173).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we did not propose to revise the payment adjustment amount for CY 2022.

The comments and our responses to the comments are set forth below.

Comment: Some commenters requested that we re-evaluate our payment adjustment for a new NTIOL class. Commenters noted that our $50 payment adjustment has not been adjusted since CY 1999 and that the stagnant payment adjustment has been a barrier to intraocular lens innovation. One commenter requested that the $50 be inflated to 2022 dollars and updated by inflation in subsequent years. Another commenter requested that the $50 payment adjustment be increased to $100.

Response: We thank the commenter for their recommendations. We did not propose revising the payment adjustment amount for CY 2022. However, we will take the commenters' recommendations into consideration in future rulemaking.

4. Announcement of CY 2022 Deadline for Submitting Requests for CMS Review of Applications for a New Class of NTIOLS

In accordance with § 416.185(a) of our regulations, CMS announces that in order to be considered for payment effective beginning in CY 2023, requests for review of applications for a new class of new technology IOLs must be received by 5:00 p.m. EST, on March 1, 2022. Send requests via email to *outpatientpps@cms.hhs.gov* or by mail to ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. To be considered, requests for NTIOL reviews must include the information requested on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs*.

F. ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 ASC final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment

methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators included in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NI'' is used in the OPPS/ASC final rule to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622).

The comment indicator ''NP'' is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed payment indicator assigned is subject to comment. The comment indicator ''NP'' also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, and the proposed payment indicator assigned is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The ''CH'' comment indicator is used in Addenda AA and BB to the proposed rule (these addenda are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example if an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in this final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

In the CY 2021 OPPS/ASC final rule with comment period, we finalized the addition of ASC payment indicator ''K5''—Items, Codes, and Services for which pricing information and claims data are not available. No payment made.—to ASC Addendum DD1 (which is available via the internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.

2. ASC Payment and Comment Indicators for CY 2022

For 2022, we proposed new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Therefore, proposed Category I and III CPT codes that are new and revised for CY 2022 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2022, compared to the CY 2021 descriptors, are included in ASC Addenda AA and BB to the CY 2022 OPPS/ASC proposed rule and labeled with proposed comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes are open for comment as part of the CY 2022 OPPS/ASC proposed rule. Proposed comment indicator ''NP'' meant a new code for the next calendar year or an existing code with substantial revision to its code descriptor in the next calendar year, as compared to the current calendar year; and denoted that comments would be accepted on the proposed ASC payment indicator for the new code.

We noted in the CY 2022 OPPS/ASC proposed rule that we would respond to public comments on ASC payment and comment indicators and finalize them in this CY 2022 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 of the CY 2022 OPPS/ASC proposed rule (these addenda are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2022 update. Addenda DD1 and DD2 to this final rule with comment period (these addenda are available via the internet on the CMS website) contain the complete list of ASC payment and comment indicators for CY 2022.

We did not receive any public comments on the proposed ASC payment and comment indicators and we are finalizing their use as proposed without modification. Addenda DD1 and DD2 to this CY 2022 OPPS/ASC final rule (theses addenda are available via the internet on the CMS website) contain the complete list of ASC payment and comment indicators for CY 2022.

G. Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007 ASC final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; § 416.171(e)).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 ASC final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment

period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.D.2. of the CY 2022 OPPS/ASC proposed rule), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 ASC final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2013/b13-01.pdf*). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we implemented the use of the CBSA delineations issued by OMB in OMB Bulletin 13–01 for the IPPS hospital wage index beginning in FY 2015.

OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. OMB Bulletin No. 15–01 made changes that are relevant to the IPPS and ASC wage index. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79750) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf*).

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58864 through 58865) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*).

On April 10, 2018, OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. A copy of OMB Bulletin No. 18–04 may be obtained at *https://www.whitehouse.gov/wpcontent/uploads/2018/90/Bulletin-18-04.pdf*. We are utilizing the revised delineations as set forth in the April 10, 2018 OMB Bulletin No. 18–03 and the September 14, 2018 OMB Bulletin No. 18–04 to calculate the CY 2021 ASC wage index effective beginning January 1, 2021.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the updates to statistical areas since September 14, 2018, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2017, and July 1, 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, one new component of an existing Combined Statistical Area and changes to New England City and Town Area (NECTA) delineations. In the CY 2022 OPPS/ASC proposed rule (86 FR 42228 through 42229), we inadvertently failed to note that OMB Bulletin No. 20–01 had revised certain statistical area delineation; however, after reviewing OMB Bulletin No. 20–01, we have determined that the changes in Bulletin 20–01 encompassed delineation changes that had no effect on the ASC wage index for CY 2022. Specifically, the updates consisted of changes to NECTA delineations and the redesignation of a single rural county into a newly created Micropolitan Statistical Area. The ASC wage indexes do not utilize NECTA definitions, and we include hospitals located in Micropolitan Statistical Areas in each state's rural wage index. Therefore, we note that these OMB updates would not affect any geographic areas for purposes of the ASC wage index calculation for CY 2022.

The final CY 2022 ASC wage indexes fully reflects the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin Nos. 15–01, 17–01, 18–03, 18–04, and 20–01). We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area.

For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). For example, for CY 2022, we are applying a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA).

When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, we determine the ASC wage index by calculating the average of all wage indexes for urban areas in the state (75 FR 72058 through 72059). In other situations, where there are no IPPS hospitals located in a relevant labor market area, we have continued our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.

Comment: Several commenters recommended that we refrain from wage-adjusting the device portion of device-intensive procedures by the wage index for that particular area and only wage-adjust non device portions of the ASC payment rate. The commenters contend that wage-adjusting 50 percent of the ASC payment rate by the wage index for a particular area can reduce ASC payment rates below the cost of certain devices.

Response: We appreciate the commenters recommendation. We did not propose such a change to our application of the ASC wage index but, as we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59042), we will consider the feasibility of this change and take this comment into consideration for future rulemaking.

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2022 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). The OPPS relative payment weights are scaled to maintain budget neutrality for the OPPS. We then scale the OPPS relative payment weights again to establish the ASC relative payment weights. To accomplish this, we hold estimated total ASC payment levels constant between calendar years for purposes of maintaining budget neutrality in the ASC payment system. That is, we apply the weight scalar to ensure that projected expenditures from the updated ASC payment weights in the ASC payment system are equal to what would be the current expenditures based on the scaled ASC payment weights. In this way we ensure budget neutrality and that the only changes to total payments to ASCs result from increases or decreases in the ASC payment update factor.

Where the estimated ASC expenditures for an upcoming year are higher than the estimated ASC expenditures for the current year, the ASC weight scalar is reduced, in order to bring the estimated ASC expenditures in line with the expenditures for the baseline year. This frequently results in ASC relative payment weights for surgical procedures that are lower than the OPPS relative payment weights for the same procedures for the upcoming year. Therefore, over time, even if procedures performed in the HOPD and ASC receive the same update factor under the OPPS and ASC payment system, payment rates under the ASC payment system would increase at a lower rate than payment for the same procedures performed in the HOPD as a result of applying the ASC weight scalar to ensure budget neutrality.

As discussed in section II.A.1.a of the CY 2022 OPPS/ASC proposed rule, given our concerns with CY 2020 claims data as a result of the PHE, we are using the CY 2019 claims data to be consistent with the OPPS claims data for the CY 2022 OPPS/ASC proposed rule. Consistent with our established policy, we proposed to scale the CY 2022 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2019, we proposed to compare the total payment using the CY 2021 ASC relative payment weights with the total payment using the CY 2022 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2021 and CY 2022. We proposed to use the ratio of CY 2021 to CY 2022 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2022. The proposed CY 2022 ASC weight scalar is 0.8591. Based on updated data for this final rule with comment period, the final CY 2022 ASC weight scalar is 0.8552. Consistent with historical practice, we would scale the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. While we would ordinarily use CY 2020 claims data to model the budget neutrality adjustment for the CY 2022 OPPS/ASC final rule, as discussed in Section X.E. of this final rule, we are finalizing our proposal to use, in general, CY 2019 claims data to model our budget neutrality adjustment. At the time of the CY 2022 OPPS/ASC proposed rule, we had available 100 percent of CY 2019 ASC claims data.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider-level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier-level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY

2022, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2019 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2022 ASC wage indexes. Specifically, holding CY 2019 ASC utilization, service-mix, and the proposed CY 2022 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2021 ASC wage indexes and the total adjusted payment using the proposed CY 2022 ASC wage indexes. We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2021 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2022 ASC wage indexes and applied the resulting ratio of 0.9999 (the proposed CY 2022 ASC wage index budget neutrality adjustment) to the CY 2021 ASC conversion factor to calculate the proposed CY 2022 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI–U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii)), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized our proposal to apply the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we will assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a productivity-adjusted hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. In addition, we finalized our proposal to revise our regulations under § 416.171(a)(2), which address the annual update to the ASC conversion factor. During this 5-year period, we intend to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and could propose a plan to collect such information. We refer readers to that final rule for a detailed discussion of the rationale for these policies.

The proposed hospital market basket update for CY 2022 was projected to be 2.5 percent, as published in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25435), based on IHS Global Inc.'s (IGI's) 2020 fourth quarter forecast with historical data through the third quarter of 2020.

Section 1886(b)(3)(B)(xi)(II) of the Act, defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). We finalized the methodology for calculating the productivity adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). The proposed productivity adjustment for CY 2022 was projected to be 0.2 percentage point, as published in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25435) based on IGI's 2020 fourth quarter forecast.

For 2022, we proposed to utilize the hospital market basket update of 2.5 percent reduced by the productivity adjustment of 0.2 percentage point, resulting in a productivity-adjusted hospital market basket update factor of 2.3 percent for ASCs meeting the quality reporting requirements. Therefore, we proposed to apply a 2.3 percent productivity-adjusted hospital market basket update factor to the CY 2021 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2022 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet the ASCQR Program requirements. We refer readers to section XIV.E. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59138 through 59139) and section XIV.E. of the CY 2022 OPPS/ASC proposed rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements. We proposed to utilize the hospital market basket update of 2.5 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then reduced by the 0.2 percentage point productivity adjustment. Therefore, we proposed to apply a 0.3 percent productivity-adjusted hospital market basket update factor to the CY 2021 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also proposed that if more recent data are subsequently available (for example, a more recent estimate of the hospital market basket update or productivity adjustment), we would use such data, if appropriate, to determine the CY 2022 ASC update for this final rule with comment period.

For 2022, we proposed to adjust the CY 2021 ASC conversion factor ($48.952) by the proposed wage index budget neutrality factor of 0.9993 in addition to the productivity-adjusted hospital market basket update of 2.3 percent discussed above, which results in a proposed CY 2022 ASC conversion factor of $50.043 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2021 ASC conversion factor ($48.952) by the proposed wage index budget neutrality factor of 0.9993 in addition to the quality reporting/productivity-adjusted hospital market basket update of 0.3 percent discussed above, which results in a proposed CY 2022 ASC conversion factor of $49.064.

The comments we received on our proposals for updating the CY 2022 ASC conversion factor and our responses are set forth below.

Comment: Commenters supported continued use of the hospital market basket for updating ASC payments on an annual basis and suggested that using the hospital market basket better aligns the OPPS and ASC payment system. One commenter requested that we permanently use the hospital market basket to update ASC payment rates rather than limiting such update factor through CY 2023.

Response: We thank the commenters for their support of our proposal. We believe using the same update factor to calculate payments to ASC and hospital outpatient departments encourages the migration of services from the hospital setting to the ASC setting, and could potentially increase the presence of ASCs in health care markets or geographic areas where previously there were none or few. The migration of services from the higher cost hospital

outpatient setting to the ASC setting is likely to result in savings to beneficiaries and the Medicare program. This policy will also further our goal of giving both physicians and beneficiaries a greater choice in selecting the care setting that best suits their needs.

As we discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized our policy to apply the hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we will assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. We intend to publish our assessment of service migration and other factors as a result of the hospital market basket update and any proposals related to our results in the CY 2023 OPPS/ASC proposed rule.

After consideration of the public comments we received, consistent with our proposal that if more recent data are subsequently available (for example, a more recent estimate of the hospital market basket update and productivity adjustment), we would use such data, if appropriate, to determine the CY 2022 ASC update for the CY 2022 OPPS/ASC final rule with comment period, we are incorporating more recent data to determine the final CY 2022 ASC update. Therefore, for this final rule with comment period, the hospital market basket update for CY 2022 is 2.7 percent, as published in the FY 2022 IPPS/LTCH PPS final rule (86 FR 42343), based on IGI's 2021 second quarter forecast with historical data through the first quarter of 2021. The productivity adjustment for this CY 2022 OPPS/ASC final rule with comment period is 0.7 percentage point, as published in the FY 2022 IPPS/LTCH PPS final rule (84 FR 42343) based on IGI's 2021 second quarter forecast.

For CY 2022, we are finalizing the hospital market basket update of 2.7 percent minus the productivity adjustment of 0.7 percentage point, resulting in a productivity-adjusted hospital market basket update factor of 2.0 percent for ASCs meeting the quality reporting requirements. Therefore, we apply a 2.0 percent productivity-adjusted hospital market basket update factor to the CY 2021 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2022 ASC payment rates. We are finalizing the hospital market basket update of 2.7 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then subtract the 0.7 percentage point productivity adjustment. Therefore, we apply a 0.0 percent productivity -adjusted hospital market basket update factor to the CY 2021 ASC conversion factor for ASCs not meeting the quality reporting requirements.

For CY 2022, we are adjusting the CY 2021 ASC conversion factor ($48.952) by a wage index budget neutrality factor of 0.9997 in addition to the productivity-adjusted hospital market basket update of 2.0 percent, discussed above, which results in a final CY 2022 ASC conversion factor of $49.916 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we are adjusting the CY 2021 ASC conversion factor ($48.952) by the wage index budget neutrality factor of 0.9997 in addition to the quality reporting/productivity-adjusted hospital market basket update of 0.0 percent discussed above, which results in a final CY 2022 ASC conversion factor of $48.937.

3. Display of CY 2022 ASC Payment Rates

Addenda AA and BB to this final rule with comment period (which are available on the CMS website) display the final ASC payment rates for CY 2022 for covered surgical procedures and covered ancillary services, respectively. Historically, for those covered surgical procedures and covered ancillary services where the payment rate is the lower of the final rates under the ASC standard ratesetting methodology and the MPFS final rates, the final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the PFS rates that would be effective January 1, 2022. For a discussion of the PFS rates, we refer readers to the CY 2022 PFS final rule that is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

The final payment rates included in addenda AA and BB to this final rule with comment period reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program. These addenda contain several types of information related to the final CY 2022 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''To be Subject to Multiple Procedure Discounting'' indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

Comment: One commenter recommended that we remove the ''Y'' indicator for CPT code 64582 and not apply the multiple procedure discount as the predecessor code, CPT code 64568, was not subject to the multiple procedure discounting policy.

Response: We agree with the commenter that the predecessor code CPT code 64568 was not subject to multiple procedure discounting and that applying our discounting policy to this procedure would be inappropriate due to its high device costs. Therefore, we are removing the ''Y'' indicator for CPT code 64582 for CY 2022.

Display of the comment indicator ''CH'' in the column titled ''Comment Indicator'' indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2022. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the interim payment indicator for the new code. Display of the comment indicator ''NP'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the ASC payment indicator for the new code.

In Addendum BB, the column titled ''Drug Pass-Through Expiration during Calendar Year'' flags, through the use of an asterisk, each drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31st).

The values displayed in the column titled ''Final CY 2022 Payment Weight'' are the final relative payment weights for each of the listed services for CY 2022. The final relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not

applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the final CY 2022 payment rate displayed in the ''Final CY 2022 Payment Rate'' column, each ASC payment weight in the ''Final CY 2022 Payment Weight'' column was multiplied by the final CY 2022 conversion factor of $49.916. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment. The final CY 2022 ASC conversion factor uses the CY 2022 productivity-adjusted hospital market basket update factor of 2.0 percent (which is equal to the projected hospital market basket update of 2.7 percent reduced by a projected productivity adjustment of 0.7 percentage point).

In Addendum BB, there are no relative payment weights displayed in the ''Final CY 2022 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Final CY 2022 Payment'' column displays the final CY 2022 national unadjusted ASC payment rates for all items and services. The final CY 2022 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in 2020.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2022.

In response to public comments we received, we are finalizing an Addendum FF to this final rule with comment period as well as subsequent OPPS/ASC proposed and final rules. Addenda FF to this final rule with comment period displays the OPPS payment rate (based on the standard ratesetting methodology), the device offset percentage, and the device portion of the ASC payment rate for CY 2022 for covered surgical procedures.

XIV. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Outpatient Quality Programs—Request for Information

We aim to move fully to digital quality measurement in the Centers for Medicare & Medicaid Services (CMS) quality reporting and value-based purchasing (VBP) programs by 2025. As part of this modernization of our quality measurement enterprise, in the CY 2022 OPPS/ASC proposed rule (86 FR 42234) we issued a request for information (RFI). The purpose of this RFI was to gather broad public input solely for planning purposes for our transition to digital quality measurement. Any updates to specific program requirements related to providing data for quality measurement and reporting provisions would be addressed through future rulemaking, as necessary. This RFI contains five parts:

- Background. This part provides information on our quality measurement programs and our goal to move fully to digital quality measurement by 2025. This part also provides a summary of recent HHS policy developments that are advancing interoperability and could support our move towards full digital quality measurement.
- Definition of Digital Quality Measures (dQMs). This part provides a potential definition for dQMs. Specific requests for input are included in the section.
- Use of Fast Healthcare Interoperability Resources (FHIR®) for Current Electronic Clinical Quality Measures (eCQMs). This part provides information on current activities underway to align CMS eCQMs with the FHIR standard and support quality measurement via application programming interfaces (APIs), and contrasts this approach to current eCQM standards and practice.
- Changes Under Consideration to Advance Digital Quality Measurement: Potential Actions in Four Areas to Transition to dQMs by 2025. This part introduces four possible steps that would enable transformation of CMS' quality measurement enterprise to be fully digital by 2025. Specific requests for input are included in the section.
- Solicitation of Comments. This part lists all requests for input we had included in the sections of this RFI.

A. Background

As required by law, we implement quality measurement and VBP programs across a broad range of inpatient acute care, outpatient, and post-acute care (PAC) settings consistent with our mission to improve the quality of health care for Americans through measurement, transparency, and increasingly, value-based purchasing. These quality programs are foundational for incentivizing value-based care, contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice. In October 2017, we launched the Meaningful Measures Framework. This framework for quality measurement captures our vision to better address health care quality priorities and gaps, including emphasizing digital quality measurement, reducing measurement burden, and promoting patient perspectives, while also focusing on modernization and innovation. The scope of the Meaningful Measures Framework evolves as the health care environment continues to change.[201] Consistent with the Meaningful Measures Framework, we aim to move fully to digital quality measurement by 2025. We acknowledge facilities within the various care and practice settings covered by our quality programs may be at different stages of readiness and, therefore, the timeline for achieving full digital quality measurement across our quality reporting programs may vary.

[201] Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

We also continue to evolve the Medicare Promoting Interoperability Program's focus on the use of certified electronic health record (EHR) technology, from an initial focus on electronic data capture to enhancing information exchange and expanding quality measurement (83 FR 41634). However, reporting data for quality measurement via EHRs remains burdensome, and our current approach to quality measurement does not readily incorporate emerging data sources such as patient-reported outcomes (PRO) and patient-generated health data (PGHD).[202] There is a need to streamline our approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning.

Additionally, advancements in technical standards and associated regulatory initiatives to improve interoperability of healthcare data are creating an opportunity to significantly improve our quality measurement systems. In May 2020, we finalized interoperability requirements in the CMS Interoperability and Patient Access final rule (85 FR 25510) to support beneficiary access to data held by certain payers. At the same time, the Office of the National Coordinator for Health Information Technology (ONC) finalized policies in the ONC 21st Century Cures Act final rule (85 FR 25642) to advance the interoperability of health information technology (IT) as defined in section 4003 of the 21st Century Cures Act, including the ''complete access, exchange, and use of all electronically accessible health information.'' Closely working with ONC, we collaboratively identified Health Level 7 (HL7®) FHIR Release 4.0.1 as the standard to support API policies in both rules. ONC, on behalf of HHS, adopted the HL7 FHIR Release 4.0.1 for APIs and related implementation specifications at 45 CFR 170.215. We believe the FHIR standard has the potential to be a more efficient and modular standard to enable APIs. We also believe this standard enables collaboration and information sharing, which is essential for delivering high-quality care and better outcomes at a lower cost. By aligning technology requirements for payers, health care facilities, and health IT developers HHS can advance an interoperable health IT infrastructure that ensures healthcare facilities and patients have access to health data when and where it is needed.

In the ONC 21st Century Cures Act final rule, ONC adopted a ''Standardized API for Patient and Population Services'' certification criterion for health IT that requires the use of FHIR Release 4 and several implementation specifications. Health IT certified to this criterion will offer single patient and multiple patient services that can be accessed by third party applications (85 FR 25742).[203] The ONC 21st Century Cures Act final rule also requires health IT developers to update their certified health IT to support the United States Core Data for Interoperability (USCDI) standard.[204] The scope of patient data identified in the USCDI and the data standards that support this data set are expected to evolve over time, starting with data specified in Version 1 of the USCDI. In November 2020, ONC issued an interim final rule with comment period extending the date when health IT developers must make technology meeting updated certification criteria available under the ONC Health IT Certification Program until December 31, 2022 (85 FR 70064).[205]

The CMS Interoperability and Patient Access final rule (85 FR 25510) and program policies build on the ONC 21st Century Cures Act final rule (85 FR 25642). The CMS Interoperability and Patient Access final rule and policies require certain payers (for example, Medicare Advantage organizations, Medicaid and Child Health Insurance Program (CHIP) Fee-for-Service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and issuers of certain Qualified Health Plan (QHP) on the Federally-facilitated Exchanges (FFEs)) to implement and maintain a standards-based Patient Access API using HL7 FHIR Release 4.0.1 to make available claims and encounter data to their enrollees and beneficiaries (called ''patients'' in the CMS interoperability rule) with the intent of ensuring enrollees and beneficiaries have access to their own health care information through third-party software applications.

The CMS Interoperability and Patient Access final rule also established new conditions of participation for Medicare and Medicaid participating hospitals and critical access hospitals (CAHs), requiring them to send electronic notifications to another healthcare facility or community provider or practitioner when a patient is admitted, discharged, or transferred (85 FR 25603).

In the calendar year (CY) 2021 Physician Fee Schedule (PFS) final rule (85 FR 84472), we finalized a policy to align the certified EHR technology required for use in the Promoting Interoperability Programs and the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category with the updates to health IT certification criteria finalized in the ONC 21st Century Cures Act final rule. Under this policy, MIPS eligible clinicians, and eligible hospitals and CAHs participating in the Promoting Interoperability Programs, must use technology meeting the updated certification criteria for performance and reporting periods beginning in 2023 (85 FR 84825).

The use of APIs can also reduce long-standing barriers to quality measurement. Currently, health IT developers are required to implement individual measure specifications within their health IT products. The health IT developer must also accommodate how that product connects with the unique variety of systems within a specific care setting.[206] This may be further complicated by systems that integrate a wide range of data schemas. This process is burdensome and costly, and it is difficult to reliably obtain high quality data across systems. As health IT developers map their health IT data to the FHIR standard and related implementation specifications, APIs can enable these structured data to be easily accessible for quality measurement or other use cases, such as care coordination, clinical decision support, and supporting patient access.

We believe the emerging data standardization and interoperability enabled by APIs will support the transition to full digital quality measurement by 2025, and are committed to exploring and seeking input on potential solutions for the transition to digital quality measurement as described in this RFI.

[202] What are patient generated health data: *https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data*.

[203] Application Programming Interfaces (API) Resource Guide, Version 1.0. Available at: *https://www.healthit.gov/sites/default/files/page/2020-11/API-Resource-Guide_v1_0.pdf*.

[204] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi*.

[205] Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the Covid-19 Public Health Emergency. Available at: *https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24376.pdf*.

[206] The Office of the National Coordinator for Health Information Technology, Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, Final Report (Feb. 2020). Available at: *https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf*.

B. Definition of Digital Quality Measures

In the proposed rule, we sought to refine the definition of digital quality measures (dQMs) to further operationalize our objective of fully transitioning to dQMs by 2025. We previously noted dQMs use ''sources of health information that are captured and can be transmitted electronically and via interoperable systems'' (85 FR 84845). In the RFI, we sought input on future elaboration that would define a dQM as a software that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources. We also note that dQMs are intended to improve the patient experience including quality of care, improve the health of populations, and/or reduce costs.

We discussed one potential approach to developing dQM software in section XIV.D.2. of the preamble of the CY 2022 OPPS/ASC proposed rule (86 FR 42235) and in this final rule with comment period. In that section, we sought comment on the potential definition of dQMs in this RFI.

We also sought feedback on how leveraging advances in technology (for example, FHIR-based APIs) to access and electronically transmit interoperable data for dQMs could reinforce other activities to support quality measurement and improvement (for example, the aggregation of data across multiple data sources, rapid-cycle feedback, and alignment of programmatic requirements).

The transition to dQMs relies on advances in data standardization and interoperability. As providers and payers work to implement the required advances in interoperability over the next several years, we will continue to support reporting of eCQMs through CMS quality reporting programs and through the Promoting Interoperability Programs.[207] These fully digital measures continue to be important drivers of interoperability advancement and learning. As discussed in the CY 2022 OPPS/ASC proposed rule and the next section of this final rule with comment period, we are currently re-specifying and testing these measures to use FHIR rather than the currently adopted Quality Data Model (QDM) in anticipation of the wider use of FHIR standards. We intend to apply significant components of the output of this work, such as the re-specified measure logic and the learning done through measure testing with FHIR-based APIs, to define and build future dQMs that take advantage of the expansion of standardized, interoperable data.

C. Use of FHIR for Current eCQMs

Since we adopted eCQMs in our hospital and clinician quality programs, we have heard from stakeholders about the technological challenges, burden, and related costs of reporting eCQM data. The CMS eCQM Strategy Project engaged with stakeholders through site visits and listening sessions with health systems and provider organizations to learn about their experiences. This stakeholder feedback identified recommendations to improve processes related to alignment; development; implementation and reporting; certification; and communication, education, and outreach. Over the past 2 years, we have focused on opportunities to streamline and modernize quality data collection and reporting processes, such as exploring FHIR (*http://hl7.org/fhir*) as a framework for measure structure and data submission for quality reporting programs, specifically for eCQMs. FHIR is a free and open source standards framework (in both commercial and government settings) created by HL7 International that establishes a common language and process for all health information technology. FHIR allows systems to communicate and information to be shared seamlessly, with a lower burden for hospitals, providers, clinicians, vendors, and quality measurement stakeholders. Specifically, for quality reporting, FHIR enables representing the data in eCQMs as well as provides a structure for eCQMs and reporting, using FHIR as the standard for all. Whereas today, multiple standards being used to report eCQMs is challenging and burdensome.

We are working to convert current eCQMs to the FHIR standard. We are currently testing the exchange of data elements represented in FHIR to CMS through ongoing HL7 Connectathons and integrated system testing by using and refining implementation guides (IGs). Submitting data through FHIR-based APIs has the potential to improve data exchange by providing consistent security, performance, scalability, and structure to all users. In addition, development of FHIR-based APIs could decrease provider burden by automating more of the measure data collection process. We continue to explore and expand potential applications of the FHIR standard and testing with eCQM use cases, and we are strongly considering a transition to FHIR-based quality reporting with the use of the FHIR standard for eCQMs in quality and value-based reporting programs. As we move to an all-dQM format for quality programs, we are depending on testing results and community readiness to improve interoperability, reduce burden, and facilitate better patient care. We will continue to consider how to leverage the interoperability advantages offered by the FHIR standards and API-based data submission, including digital quality measurement.

D. Changes Under Consideration To Advance Digital Quality Measurement: Potential Actions in Four Areas To Transition to Digital Quality Measures by 2025

Building on the advances in interoperability and learning from testing of FHIR-converted eCQMs, we aim to move fully to dQMs, originating from sources of health information that are captured and can be transmitted electronically via interoperable systems, by 2025.

To enable this transformation, we are considering further modernization of the quality measurement enterprise in four major ways: (1) Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs; (2) redesign our quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across our reporting programs, other Federal programs and agencies, and the private sector where appropriate.

These changes would enable us to collect and utilize more timely, actionable, and standardized data from diverse sources and care settings to improve the scope and quality of data used in quality reporting and payment programs, reduce quality reporting burden, and make results available to stakeholders in a rapid-cycle fashion. Data collection and reporting efforts would become more efficient, supported by advances in interoperability and data standardization. Aggregation of data from multiple sources would allow assessments of costs and outcomes to be measured across multiple care settings for an individual patient or clinical conditions. We believe that aggregating data for measurement can incorporate a more holistic assessment of an individual's health and health care and produce the rich set of data needed to

[207] eCQI Resource Center. Available at: *https://ecqi.healthit.gov/*.

enable patients and caregivers to make informed decisions by combining data from multiple sources (for example, patient reported data, EHR data, and claims data) for measurement.

Perhaps most importantly, these steps would help us deliver on the full promise of quality measurement and drive us toward a learning health system that transforms healthcare quality, safety, and coordination and effectively measures and achieves value-based care. The shift from a static to a learning health system hinges on the interoperability of healthcare data, and the use of standardized data. The dQMs would leverage this interoperability to deliver on the promise of a learning health system wherein standards-based data sharing and analysis, rapid-cycle feedback, and quality measurement and incentives are aligned for continuous improvement in patient-centered care. Similarly, standardized, interoperable data used for measurement can also be used for other use cases, such as clinical decision support, care coordination and care decision support, which impacts health care and care quality.

We requested comments on four potential future actions that would enable transformation to a fully digital quality measurement enterprise by 2025.

1. Leveraging and Advancing Standards for Digital Data and Obtaining All EHR Data Required for Quality Measures via Provider FHIR-Based APIs

We are considering targeting the data required for our quality measures that utilize EHR data to be data retrieved via FHIR-based APIs based on standardized, interoperable data. Utilizing standardized data for EHR-based measurement (based on FHIR and associated IGs) and aligning where possible with interoperability requirements can eliminate the data collection burden providers currently experience with required chart-abstracted quality measures and reduce the burden of reporting digital quality measure results. We can fully leverage this advance to adapt eCQMs and expand to other dQMs through the adoption of interoperable standards across other digital data sources. We are considering methods and approaches to leverage the interoperability data requirements for APIs in certified health IT set by the ONC 21st Century Cures Act final rule to support modernization of CMS quality measure reporting. As discussed previously, these requirements will be included in certified technology in future years (85 FR 84825) including availability of data included in the USCDI via standards-based APIs, and we will require clinicians and hospitals participating in MIPS and the Promoting Interoperability Programs, respectively, to transition to use of certified technology updated consistent with the 2015 Cures Edition Update (85 FR 84825).

Digital data used for measurement could also expand beyond data captured in traditional clinical settings, administrative claims data, and EHRs. Many important data sources are not currently captured digitally, such as survey and PGHD. We intend to work to innovate and broaden the digital data used across the quality measurement enterprise beyond the clinical EHR and administrative claims. Agreed upon standards for these data, and associated implementation guides will be important for interoperability and quality measurement. We will consider developing clear guidelines and requirements for these digital data that align with interoperability requirements, for example, requirements for expressing data in standards, exposing data via standards-based APIs, and incentivizing technologies that innovate data capture and interoperability.

High quality data are also essential for reliable and valid measurement. Hence, in implementing the shift to collect all clinical EHR data via FHIR-based APIs, we would support efforts to strengthen and test the quality of the data obtained through FHIR-based APIs for quality measurement. We currently conduct audits of eCQM data submitted under our quality programs, including the Hospital Inpatient Quality Reporting (IQR) Program, with functions including checks for data completeness and data accuracy, confirmation of proper data formatting, alignment with standards, and appropriate data cleaning (82 FR 38398 through 38402). These functions would continue and be applied to dQMs and further expanded to automate the manual validation of the data compared to the original data source (for example, the medical record) where possible. Analytic advancements such as natural language processing, big data analytics, and artificial intelligence, can support this evolution. These techniques can be applied to validating observed patterns in data and inferences or conclusions drawn from associations, as data are received, to ensure high quality data are used for measurement.

We sought feedback on the goal of aligning data needed for quality measurement with interoperability requirements and the strengths and limitations of this approach. We also sought feedback on the importance of and approaches to supporting inclusion of PGHD and other currently non-standardized data. We also welcomed comment on approaches for testing data quality and validity.

2. Redesigning Quality Measures To Be Self-Contained Tools

We are considering approaches for including quality measures that take advantage of standardized data and interoperability requirements that have expanded flexibility and functionality compared to CMS' current eCQMs. We are considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR-based resources maintained by providers, payers, CMS, and others; calculate measure score(s); and produce reports. In general, we believe to optimize the use of standardized and interoperable data, the software solution for dQMs should do the following:

- Have the flexibility to support calculation of single or multiple quality measure(s).
- Perform three functions—

++ Obtain data via automated queries from a broad set of digital data sources (initially from EHRs, and in the future from claims, PRO, and PGHD);

++ Calculate the measure score according to measure logic; and

++ Generate measure score report(s).

- Be compatible with any data source systems that implement standard interoperability requirements.
- Exist separately from digital data source(s) and respect the limitations of the functionality of those data sources.
- Be tested and updated independently of the data source systems.
- Operate in accordance with health information protection requirements under applicable laws and comply with governance functions for health information exchange.
- Have the flexibility to be deployed by individual health systems, health IT vendors, data aggregators, and health plans; and/or run by CMS depending on the program and measure needs and specifications.
- Be designed to enable easy installation for supplemental uses by medical professionals and other non-technical end-users, such as local calculation of quality measure scores or quality improvement.
- Have the flexibility to employ current and evolving advanced analytic approaches such as natural language processing.
- Be designed to support pro-competitive practices for development, maintenance, and implementation as

well as diffusion of quality measurement and related quality improvement and clinical tools through, for example, the use of open-source core architecture.

We sought comment on these suggested functionalities and other additional functionalities that quality measure tools should ideally have particularly in the context of the possible expanding availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs).

We were also interested whether and how this more open, agile strategy may facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research.

3. Building a Pathway to Data Aggregation in Support of Quality Measurement

Using multiple sources of collected data to inform measurement would reduce data fragmentation (or, different pieces of data regarding a single patient stored in many different places). Additionally, we are considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators that include, but are not limited to, HIEs and clinical registries. Qualified Clinical Data Registries and Qualified Registries that report quality measures for eligible clinicians in the MIPS program are potential examples [208] at 42 CFR 414.1440(b)(2)(iv) and (v) and (c)(2)(iii) and (iv) and can also support measure reporting. We are considering establishing similar policies for third-party aggregators to maintain the integrity of our measure reporting process and to encourage market innovation.

We sought feedback on aggregation of data from multiple sources to inform measurement and potential policy considerations. We also sought feedback on the role data aggregators can and should play in CMS quality measure reporting in collaboration with providers, and how we can best facilitate and enable aggregation.

4. Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

We are committed to using policy levers and working with stakeholders to solve the issue of interoperable data exchange and to transition to full digital quality measurement. We are considering the future potential development and multi-staged implementation of a common portfolio of dQMs across our regulated programs, agencies, and private payers. This common portfolio would require alignment of: (1) Measure concepts and specifications including narrative statements, measure logic, and value sets; and (2) the individual data elements used to build these measure specifications and calculate the measure logic. Further, the required data elements would be limited to standardized, interoperable data elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and IGs for key data elements. We would coordinate closely with quality measure developers, Federal and state agencies, and private payers to develop and to maintain a cohesive dQM portfolio that meets our programmatic requirements and that fully aligns across Federal and state agencies and payers to the extent possible.

We intend for this coordination to be ongoing and allow for continuous refinement to ensure quality measures remain aligned with evolving healthcare practices and priorities (for example, PROs, disparities, and care coordination), and track with the transformation of data collection, alignment with health IT module updates including capabilities and standards adopted by ONC (for example, standards to enable APIs). This coordination would build on the principles outlined in HHS' National Health Quality Roadmap.[209] It would focus on the quality domains of safety, timeliness, efficiency, effectiveness, equitability, and patient-centeredness. It would leverage several existing Federal and public-private efforts including our Meaningful Measures 2.0 Framework; the Federal Electronic Health Record Modernization (Department of Defense and Veterans Affairs (DoD/VA)); the Agency for Healthcare Research and Quality's (AHRQ) Clinical Decision Support Initiative; the Centers for Disease Control and Prevention's (CDC) Adapting Clinical Guidelines for the Digital Age initiative; Core Quality Measure Collaborative, which convenes stakeholders from America's Health Insurance Plans (AHIP), CMS, National Quality Forum (NQF), provider organizations, private payers, and consumers and develops consensus on quality measures for provider specialties; and the NQF-convened Measure Applications Partnership (MAP), which recommends measures for use in public payment and reporting programs. We would coordinate with HL7's ongoing work to advance FHIR resources in critical areas to support patient care and measurement such as social determinants of health. Through this coordination, we would identify which existing measures could be used or evolved to be used as dQMs, in recognition of current healthcare practice and priorities.

This multi-stakeholder, joint Federal, state, and industry effort, made possible and enabled by the pending advances towards true interoperability, would yield a significantly improved quality measurement enterprise. The success of the dQM portfolio would be enhanced by the degree to which the measures achieve our programmatic requirements for measures as well as the requirements of other agencies and payers.

We sought feedback on initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools, and data standards). We also sought to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities across sectors.

E. Solicitation of Comments

As noted previously, we sought input on the future development of the following in the CY 2022 OPPS/ASC proposed rule (86 FR 42232):

- Definition of Digital Quality Measures. We sought feedback on the following as described in section XIV.2. of the CY 2022 OPPS/ASC proposed rule:

++ Do you have feedback on the potential future dQM definition?

++ Does this approach to defining and deploying dQMs to interface with FHIR-based APIs seem promising? We also welcomed more specific comments on the attributes or functions to support such an approach of deploying dQMs.

- Use of FHIR for Current eCQMs. We sought feedback on the following as described in section XIV.3. of the

[208] CY 2021 Physician Fee Schedule Final Rule: Finalized (New and Updated) Qualified Clinical Data Registry (QCDR) and Qualified Registry Policies, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1362/QCDR%20and%20QR%20Updates%202021%20Final%20Rule%20Fact%20Sheet.pdf.*

[209] Department of Health and Human Services, National Health Quality Roadmap (May 2020). Available at: *https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf.*

preamble of the CY 2022 OPPS/ASC proposed rule:

++ Would a transition to FHIR-based quality reporting reduce burden on health IT vendors and providers? Please explain.

++ Would access to near real-time quality measure scores benefit your practice? How so?

++ What parts of the current CMS Quality Reporting Data Architecture (QRDA) IGs cause the most burden (please explain the primary drivers of burden)?

++ In what ways could CMS FHIR Reporting IG be modified to reduce burden on providers and vendors?

• Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025.

++ We sought feedback on the following as described in section XIV.4.a. of the preamble of the CY 2022 OPPS/ASC proposed rule:

—Do you agree with the goal of aligning data needed for quality measurement with interoperability requirements? What are the strengths and limitations of this approach? Are there specific FHIR IGs suggested for consideration?

—How important is a data standardization approach that also supports inclusion of PGHD and other currently non-standardized data?

—What are possible approaches for testing data quality and validity?

++ We sought feedback on the following as described in section XIV.4.b. of the preamble of the CY 2022 OPPS/ASC proposed rule:

—What functionalities, described in section (4)(b) or others, should quality measure tools ideally have in the context of the pending availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs)?

—How would this more open, agile strategy for end-to-end measure calculation facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research?

++ We sought feedback on the following as described in section XIV.4.c. of the preamble of the CY 2022 OPPS/ASC proposed rule:

—What are key policy considerations for aggregation of data from multiple sources being used to inform measurement?

—What role can or should data aggregators play in CMS quality measure reporting in collaboration with providers? How can CMS best facilitate and enable aggregation?

++ We sought feedback on the following as described in section XIV.4.d. of the preamble of the CY 2022 OPPS/ASC proposed rule:

—What are initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools)?

—We also sought to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities and across sectors.

We requested commenters to consider provisions in the CMS Interoperability and Patient Access final rule (85 FR 25510), CMS CY 2021 PFS final rule (85 FR 84472), and the ONC 21st Century Cures Act final rule (85 FR 25642).

We plan to continue working with other agencies and stakeholders to coordinate and to inform any potential transition to dQMs by 2025. While we will not be responding to specific comments submitted in response to this Request for Information in this final rule with comment period, we will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

We received comments on these topics:

Comment: There was widespread support among commenters for digital quality measurement in general. Many commenters specifically expressed support for CMS' transition to digital quality measurement. Some commenters noted digital quality measurement holds promise to improve the quality measurement enterprise, and patient outcomes and experience; reduce administrative burden; and make meaningful data more readily available for quality improvement. Commenters encouraged CMS to set up incentives for those who participate in digital measurement to help prepare their facilities' technology for the change, as well as incentives for reporting their quality data. Commenters noted CMS must plan for and design digital quality measure requirements while considering the availability of data standards, data security, and technical infrastructure and capabilities.

However, a few commenters did not fully support CMS' transition to digital measurement, for example, due to lack of readiness, technical capabilities, or specificity from CMS about the transition plan. The commenters expressed concerns with the readiness of ASCs and their informational technology capabilities. Another commenter strongly opposed CMS' access to a facility's EHR for measurement. The commenter noted technological challenges in the outpatient setting and administrative burdens as made evident and exacerbated by the COVID–19 public health emergency.

Regarding the timeline for the transition to digital quality measurement, while some commenters agreed the 2025 timeline is feasible, some questioned the feasibility of the full transition by 2025. Commenters who were hesitant about the 2025 timeline noted the timeline is ambitious or aggressive. Some noted the timeline is ambitious due to the burden facilities have incurred through the COVID–19 public health emergency. Others noted the timeline is impractical for ASCs since ASCs were not included in the provisions of the American Recovery and Reinvestment Act of 2009, which established provisions to encourage adoption of EHRs, and ASCs' current use of EHRs is limited. Some commenters suggested delaying the transition until after the COVID–19 Public Health Emergency (for example, 2 years after its end), while others suggested CMS revert back to the 2030 goal or delay transition until CMS can provide further guidance to stakeholders on their plans for the transition to digital measurement. Other commenters noted CMS' transition will need to account for real-world testing to ensure the availability of data, technical infrastructure, and alignment with other requirements such as ONC's CEHRT. The commenters noted CMS will need to plan for this, coordinate efforts, and encourage adoption by stakeholders particularly in underserved communities.

Response: We appreciate all of the comments on this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

In the CY 2022 OPPS/ASC proposed rule (86 FR 42232), we clarified a

potential future definition of dQMs as a software that processes digital data to produce a measure score or measure scores.

Comment: Several commenters noted appreciation for CMS' clarifications of the potential dQM definition. While some commenters supported the broad definition of dQMs and the ability of dQMs to promote rapid-cycle feedback for quality reporting, some commenters found the definition to still be too broad. A few commenters appreciated the broad range of digital data sources included in the definition and noted the definition captures the evolving availability of digital data. A few commenters who also supported the broad definition noted dQMs should and could capture data from across the continuum of care.

Some commenters who did not support the broad definition noted not all of the digital data sources in the definition have been adequately vetted or tested. The commenters noted not all of the digital data sources are currently ready to be used as reliable and valid sources for digital measurement (for example, data from wearable devices, patient-generated health data), although they hold promise for the future. Another commenter who also opposed CMS' transition to digital measurement did not support the use of emerging digital data sources, such as patient-generated health data, without specific details about CMS' plans to incorporate digital data sources in dQMs and ensuring the data would be understandable to beneficiaries.

Several commenters sought additional information and clarification regarding the definition. Specifically, several stakeholders requested further clarification on the potential definition of dQMs, how CMS envisions the future of dQMs, and how the future use of dQMs would differ from the current state. Some stakeholders requested clarification about the use of the term ''software'' in the potential dQM definition and suggested refinements to the definition. For example, one commenter who noted software development does not align with the current specification or structure of quality measures, suggested using alternative terms in the dQM definition such as ''computer readable'' or ''computer executable.'' Some commenters suggested CMS better define goals and expectations for dQM use. Some commenters requested a specific roadmap of implementation for providers to better understand how to prepare for dQMs.

Response: We appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

As noted above, we requested input on the use of FHIR for eCQMs and actions in four areas to transition to dQMs by 2025 including:

(1) Leveraging and advancing standards for digital data and obtaining all EHR data required for quality measures via provider FHIR-based APIs.

(2) Redesigning quality measures to be self-contained tools.

(3) Building a pathway to data aggregation in support of quality measurement.

(4) Potential future alignment of measures across reporting programs, Federal and state agencies, and the private sector.

Comment: Some commenters agreed FHIR-based quality reporting would reduce burden on providers. Commenters acknowledged FHIR provides a standardized way of sharing information and agreed the use of FHIR would increase interoperability and harmonization of data standards across providers and care settings. However, some commenters noted not all EHR or health IT vendors have adopted FHIR. Commenters encouraged CMS to evaluate the adoption of FHIR standard as well as understand the potential burden and costs associated with its adoption before requiring its use for digital measurement. Some commenters also requested CMS provide guidance to measure developers, vendors, and other stakeholders on the transition to FHIR-based eCQMs (for example, which version of FHIR to implement and which implementation guides will be used) and ensure sufficient testing prior to widespread adoption. One commenter agreed with incentivizing the use of FHIR but not requiring it as to not place undue burden on hospital or other providers who are not yet ready to adopt FHIR. Another commenter who did not agree with using the FHIR standard cautioned relying on any single approach or standard (for example, FHIR) until successful model elements can be identified.

Some commenters agreed with the goal of aligning data needed for quality measurement with interoperability requirements, and those data necessary for clinical care. For example, one commenter suggested using data elements in quality measures that conform to the data elements and classes in the United States Core Data for Interoperability (USCDI), where possible, to reduce measure complexity and improve data quality. A few commenters noted challenges with managing health information from unstructured data fields for digital measurement in the outpatient setting. The commenters noted some health information in the outpatient setting (for example, for anesthesia and imaging) is contained in unstructured data fields, and this would pose a challenge for FHIR-based quality measurement. Some commenters also expressed concerns about inclusion of data from sources outside of the EHR in measurement due to privacy and validity concerns. Other commenters noted that broader data sources used in measurement will improve measurement but may need to be phased in.

Regarding building a pathway to data aggregation, some commenters agreed that data aggregation will become easier with more aligned and interoperable data, and aggregation of data will strengthen measurement and provide a better understanding of population health. Other commenters requested more clarity on how third-party aggregators will be incorporated into the quality measurement ecosystem. A commenter also noted the need for a national strategy to improve patient identification and matching to facilitate more accurate data aggregation. One commenter identified the potential measure development and testing burden when combining data from multiple sources. Commenters also noted the need for increased data security as data sharing and aggregation is broadly implemented; one commenter recommended the Trusted Exchange Framework and Common Agreement (TEFCA) as a framework to support secure data sharing.

Some commenters supported using provider FHIR-based APIs for quality measurement and agreed with obtaining all EHR data captured for quality measure via provider FHIR-based APIs as a stride towards interoperability. Some commenters also requested CMS provide expectations and clarifications to ensure privacy and data security (for example, security transfer guidelines and security procedures).

However, some commenters expressed concerns about the use of FHIR-based APIs such as the technical infrastructure and financial readiness, and providers' unfamiliarity with or varied uptake of FHIR. For example, as noted above, some commenters pointed out the limited use of EHRs by ASCs. They noted that the technological

hurdles created by FHIR may prove problematic for some ASCs. Because ASCs are not required to use EHRs, stakeholders voiced that many do not use EHRs or they use EHRs that are certified. The commenters encouraged any regulations of applications be backwards compatible so as to allow more ASCs to participate. Commenters also identified the need for significant support for small ASCs or ASCS in rural or underserved areas that do not have the resource to have dedicated health IT staff. For support, commenters requested CMS provide technical assistance, advanced notice of requirements, and adequate time for rollout. A few commenters encouraged CMS to rigorously test any programs they implement to ensure patient safety and security as well as checking that systems do not cause accidental bias.

Some commenters agreed with redesigning quality measures as self-contained tools and agreed with their functionalities necessary to achieve digital quality measurement. The recommended CMS work with stakeholders to identify how and when the functionalities of the self-contained tools could be sequenced (for example, which could be achievable by 2025) and scaled. Further, commenters noted the tools should be tested and validated.

Many commenters expressed support for alignment of measurement areas, specifications, data elements used to build the specifications, and tools across reporting programs and payers. Several commenters noted alignment will require input from stakeholders and leadership across federal agencies. Some commenters recommended CMS work with other federal agencies and stakeholders such as patients to understand their role as an active EHR end-user, the National Quality Forum (NQF), the health IT community, the Core Quality Measures Collaborative (CQMC), and others. Some commenters encouraged CMS to partner with ONC on data standards and interoperability requirements (for example, health IT certification requirements) to plan for validating dQMs and ensure alignment across agencies.

Several commenters supported the development of a common dQM portfolio. Some commenters suggested initial priority areas for the common dQM portfolio. For example, some commenters noted the importance of standardizing social risk factor data collection and use of social risk factor data in measurement. Some commenters suggested CMS prioritize dQMs with clinical relevance, dQMs focusing on immunizations, and dQMs for anesthesia care as well as ensure dQMs would be available to cover all medical specialties and practitioners. Some commenters encouraged CMS to identify which existing measures could be used as dQMs while concurrently identifying future priority areas. Commenters also noted alignment could leverage data routinely captured during and across the continuum of clinical care, simplify quality reporting, and help address challenges associated with managing various standards and formats.

Several commenters supported a phased approach to dQM implementation. Several commenters requested CMS allow adequate time for setting up capabilities for implementation, testing, and validation to ensure successful transition to and use of dQMs. Several commenters requested CMS provide a plan for transition to digital quality measurement and consider program incentives, flexibilities in reporting, and technical assistance for providers. One commenter suggested CMS incorporate this plan as part of their creation of the common dQM portfolio. Another commenter recommended CMS develop a staged long-term plan on digital measurement in conjunction with a long-term plan on equity. One commenter, however, expressed concern about the phased approach and noted alignment should be a priority alongside interoperability.

Many commenters expressed they are committed to working with CMS in supporting the transition to digital quality measurement.

Response: We appreciate all of the comments on this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

XV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

CMS seeks to promote higher quality and more efficient healthcare for Medicare beneficiaries. Consistent with these goals, CMS has implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program. The Hospital OQR Program regulations are codified at 42 CFR 419.46. In the CY 2021 OPPS/ASC final rule (85 FR 86179), we finalized updates to the regulations to include a reference to the statutory authority for the Hospital OQR Program. Section 1833(t)(17)(A) of the Social Security Act (the Act) states that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) that do not submit data required for measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0 percentage point reduction to their annual Outpatient Department (OPD) fee schedule increase factor. In the CY 2021 OPPS/ASC final rule (85 FR 86179) we codified the Hospital OQR Program's statutory authority at § 419.46(a).

3. Regulatory History of the Hospital OQR Program

We refer readers to the CY 2008 through 2021 OPPS/ASC final rules with comment period for detailed discussions of the regulatory history of the Hospital OQR Program:

- The CY 2008 OPPS/ASC final rule (72 FR 66860 through 66875);
- The CY 2009 OPPS/ASC final rule (73 FR 68758 through 68779);
- The CY 2010 OPPS/ASC final rule (74 FR 60629 through 60656);
- The CY 2011 OPPS/ASC final rule (75 FR 72064 through 72110);
- The CY 2012 OPPS/ASC final rule (76 FR 74451 through 74492);
- The CY 2013 OPPS/ASC final rule (77 FR 68467 through 68492);
- The CY 2014 OPPS/ASC final rule (78 FR 75090 through 75120);
- The CY 2015 OPPS/ASC final rule (79 FR 66940 through 66966);
- The CY 2016 OPPS/ASC final rule (80 FR 70502 through 70526);
- The CY 2017 OPPS/ASC final rule (81 FR 79753 through 79797);
- The CY 2018 OPPS/ASC final rule (82 FR 59424 through 59445);
- The CY 2019 OPPS/ASC final rule (83 FR 59080 through 59110);
- The CY 2020 OPPS/ASC final rule (84 FR 61410 through 61420); and
- The CY 2021 OPPS/ASC final rule (85 FR 86179 through 86187).

We have codified certain requirements under the Hospital OQR

Program at 42 CFR 419.46. We refer readers to section XV.E. of this final rule with comment period for a detailed discussion of the payment reduction for hospitals that fail to meet Hospital OQR Program requirements for the CY 2024 payment determination.

B. Hospital OQR Program Quality Measures

1. Considerations in Selecting Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. We did not propose any changes to these policies in the proposed rule.

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously finalized and codified at § 419.46(h)(1) a policy to retain measures from a previous year's Hospital OQR Program measure set for subsequent years' measure sets, unless removed (77 FR 68471 and 83 FR 59082). We did not propose any changes to these policies in the proposed rule.

3. Removal of Quality Measures From the Hospital OQR Program Measure Set

a. Immediate Removal

We previously finalized and codified at § 419.46(i)(2) and (3) a process for removal and suspension of Hospital OQR Program measures, based on evidence that the continued use of the measure as specified raises patient safety concerns (74 FR 60634 through 60635, 77 FR 68472, and 83 FR 59082).[210] We did not propose any changes to these policies in the proposed rule.

b. Consideration Factors for Removing Measures

We previously finalized and codified at § 419.46(i)(3) policies to use the regular rulemaking process to remove a measure for circumstances for which we do not believe that continued use of a measure raises specific patient safety concerns (74 FR 60635 and 83 FR 59082).[211] We did not propose any changes to these policies in the proposed rule.

c. Measure Removals Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination: OP–02 (Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival) and OP–03 (Median Time To Transfer to Another Facility for Acute Coronary Intervention)

In CY 2022 OPPS/ASC proposed rule (86 FR 42237), we proposed to remove two chart-abstracted measures under removal Factor 4—the availability of a more broadly applicable (across settings, populations, or conditions) measure for the particular topic:

- Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department (ED) Arrival (OP–2); and
- Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP–3).

The OP–2 measure assesses the number of acute myocardial infarction (AMI) patients with: (a) ST-segment elevation on the electrocardiogram closest to arrival time receiving fibrinolytic therapy during the ED visit; and (b) a time from hospital arrival to fibrinolysis of 30 minutes or less. For more details on this measure, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66865), where this measure was designated as ED–AMI–3, and the CY 2009 OPPS/ASC final rule with comment period (73 FR 68761), where this measure was relabeled as OP–2 (for the CY 2010 payment determination and subsequent years). The OP–3 measure assesses the median number of minutes before outpatients with chest pain or possible heart attack who needed specialized care were transferred to another hospital capable of offering such specialized care. For more details on this measure, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66865), where this measure was designated as ED–AMI–5, and the CY 2009 OPPS/ASC final rule with comment period (73 FR 68761), where this measure was relabeled as OP–3 (for the CY 2010 payment determination and subsequent years).

In the CY 2022 OPPS/ASC proposed rule (86 FR 42237), we proposed to remove these two measures (Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department (ED) Arrival (OP–2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP–3)) beginning with the CY 2023 reporting period/CY 2025 payment determination due to the availability of a more broadly applicable measure. Specifically, in the CY 2022 OPPS/ASC proposed rule (86 FR 42237), we proposed to adopt the ST-Segment Elevation Myocardial Infarction (STEMI) electronic clinical quality measure (eCQM) into the Hospital OQR Program measure set, which would serve as a replacement for these two measures. We refer readers to section XV.B.4.c. of the CY 2022 OPPS/ASC proposed rule (86 FR 42244) and section XV.B.4.c. of this final rule with comment period for further discussion of the STEMI eCQM, including the measure overview, data sources, and measure calculation.

OP–2 and OP–3 measure the proportion of eligible STEMI patients who receive timely fibrinolytic therapy and timely transfer from an ED to another facility to receive appropriate care, respectively. The STEMI eCQM is an electronic process measure that includes both the populations of OP–2 and OP–3. It measures the percentage of ED patients diagnosed with STEMI that received timely fibrinolytic therapy (within 30 minutes) or timely transfer to a percutaneous coronary intervention (PCI)-capable facility (within 45 minutes). Additionally, the STEMI eCQM (OP–40) captures transfer and non-transfer patients at a PCI-capable facility who receive PCI (within 90 minutes). Pursuant to removal Factor 4, we believe that the adoption of the STEMI eCQM would capture the OP–2 and OP–3 measure populations and expand beyond these populations to comprehensively measure the timeliness and appropriateness of STEMI care.

Furthermore, the OP–2 and OP–3 measures are chart-abstracted measures, which result in greater provider burden due to manual abstraction. The STEMI eCQM (OP–40) allows for the retrieval of data directly from the electronic health record (EHR) using patient-level data. As a result, in the proposed rule we stated our belief that the STEMI eCQM (OP–40) is a more broadly applicable measure and transitions the Hospital OQR Program toward the use of EHR data for quality measurement. We noted in the CY 2022 OPPS/ASC proposed rule (86 FR 42237) that removal of these measures was contingent on the finalization of the STEMI eCQM. We invited public comment on our proposals to remove these measures.

The following is a summary of the comments we received on these proposals and our responses.

Comment: Many commenters supported the proposal to remove the two chart-abstracted measures, Fibrinolytic Therapy Received Within

[210] We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our reasons for changing the term ''retirement'' to ''removal'' in the Hospital OQR Program.

[211] We initially referred to this process as ''retirement'' of a measure in the 2010 OPPS/ASC proposed rule, but later changed it to ''removal'' during final rulemaking.

30 Minutes of ED Arrival (OP–2) and Median Time To Transfer to Another Facility for Acute Coronary Intervention (OP–3), and they were favor of adopting the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM. These commenters also believed that the STEMI eCQM would reduce data collection burden and be more useful than OP–2 and OP–3.

Response: We thank the commenters for their support of our proposal to remove OP–2 and OP–3. We agree that adopting the STEMI eCQM would reduce data collection burden and would be a more broadly applicable measure that transitions the Hospital OQR Program toward the use of EHR data for quality measurement.

Comment: A few commenters supported removing OP–2 and OP–3 in favor of introducing the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM, but expressed concerns about the transition to the STEMI eCQM. One commenter noted that the STEMI eCQM had not yet been endorsed by the NQF and recommended delaying the proposed removal of OP–2 and OP–3 and the addition of the STEMI eCQM until 2024 to allow for completion of NQF review. Another commenter suggested that CMS delay removing OP–2 and OP–3 so that hospitals have time to implement the new STEMI eCQM for an additional year.

Response: We thank the commenters for their support and acknowledge their concerns. We note that, in regard to the endorsement status of the STEMI eCQM, the MAP voted to conditionally support the measure, pending NQF endorsement.[212] CMS is in the process of seeking NQF endorsement for the STEMI eCQM. We refer the reader to section XV.B.4.c. of this final rule with comment period for additional information on the adoption of the STEMI eCQM, including our rationale for adopting the measure when it has not yet been endorsed by the NQF. In response to the suggestion that removing OP–2 and OP–3 should be delayed to allow additional time for transitioning to eCQM reporting, we believe that, as we proposed the reporting of this measure to be voluntary for the CY 2023, hospitals would have sufficient time to practice and operationalize reporting in order to transition from OP–2 and OP–3 to the STEMI eCQM.

Comment: One commenter did not support removing OP–2 and OP–3 from the measure set and believed that it would increase burden for hospitals that are not equipped for electronic reporting, especially smaller and more rural facilities. The commenter stated that reporting requirements for eCQMs exceed those for chart-abstracted measures and that introducing an eCQM will require training or hiring new staff.

Response: We thank the commenter for their input. While we acknowledge that removing two chart-abstracted measures and transitioning to an eCQM may pose certain short-term challenges for hospitals, we reiterate the value of transitioning to an eCQM. That is, we believe that this transition aligns with our overall efforts to reduce regulatory burden on hospitals, lower health care costs, and enhance patient care by streamlining the quality reporting and value-based purchasing programs as stated in the Meaningful Measures Framework. We note, OP–2 and OP–3 measures are chart-abstracted measures, which generally places greater burden on the provider due to the labor and cost of manual abstraction. In contrast, the STEMI eCQM would allow for the retrieval of data directly from the electronic health record (EHR) using patient-level data, thus reducing provider burden.

We believe adoption of this proposal would place limited burden on smaller and more rural facilities. Small hospitals and facilities that do not have the volume of data required for reporting of the eCQMs will be exempt from reporting of those measures based on the case threshold exemptions outlined in section XV.D.6.d.(3) of this final rule with comment period. Additionally, the Medicare and Medicaid EHR Incentive Programs, established by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), authorized HHS to provide financial incentives to hospitals and eligible professionals for the ''meaningful use'' of certified EHR technology to improve patient care.[213] These financial incentives assisted hospitals in transitioning to the use of EHR technology.[214] Successful demonstration of meaningful use included, among other requirements, using certified EHR technology to meet specified thresholds for a number of objectives and measures and reporting clinical quality measures (CQMs). Given the exemption for facilities that do not meet case thresholds and past efforts to assist with the transition to EHR, we believe that the value added by streamlining the quality reporting and value-based purchasing programs justifies the burden these standards may place on facilities. We refer readers to section XXII.B. of this final rule with comment period for additional information on the burden calculations for removing OP–2 and OP–3 and adopting the STEMI eCQM.

After consideration of the public comments we received, we are finalizing this provision as proposed.

4. Adoption of New Measures for the Hospital OQR Program Measure Set

In the CY 2022 OPPS/ASC proposed rule (86 FR 42238), we proposed to adopt three new measures: (1) COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure, beginning with the CY 2022 reporting period; (2) Breast Cancer Screening Recall Rates measure, beginning with the CY 2022 reporting period; and (3) STEMI eCQM, beginning as a voluntary measure for the CY 2023 reporting period, and then as a mandatory measure beginning with the CY 2024 reporting period.

a. Adoption of the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination

(1) Background

On January 31, 2020, the Secretary declared a public health emergency (PHE) for the United States (U.S.) in response to the global outbreak of SARS-CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[215] COVID–19 is a contagious respiratory infection [216] that can cause serious illness and death. Older individuals, some racial and ethnic minorities, and those with underlying medical conditions are considered to be at higher risk for more serious

[212] The National Quality Forum. (2021). Measure Applications Partnership 2020–2021. Considerations for Implementing Measures in Federal Programs: Clinician, Hospital & PAC/LTC. Accessed on May 17, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94893*.

[213] Ibid.

[214] American Hospital Association. A Study of The Impact of Meaningful Use Clinical Quality Measures. Available at: *https://www.aha.org/sites/default/files/hospitals-face-challenges-using-electronic-health-records-to-generate-clinical-quality-measures.pdf*.

[215] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*.

[216] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

complications from COVID–19.[217] [218] As of July 2, 2021, the U.S. reported over 33 million cases of COVID–19 and over 600,000 COVID–19 deaths.[219] As of October 14, 2021, the U.S. reported over 44 million cases and over 718,000 COVID–19 deaths.[220] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[221] Between December 2, 2020 and January 30, 2021, more than 100,000 Americans with COVID–19 were hospitalized at the same time.[222]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[223] Ongoing research indicates that fully vaccinated people without immunocompromising conditions are able to engage in most activities with very low risk of acquiring or transmitting SARS–CoV–2, and the Centers for Disease Control and Prevention (CDC) issued new guidance for fully vaccinated individuals on May 28, 2021.[224] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[225] Thus, the CDC advises that infections mainly occur through exposure to respiratory droplets when a person is in close contact with someone who has COVID–19.[226] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface [227] and that in certain circumstances, infection can occur through airborne transmission.[228] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed COVID–19 infection, regardless of whether the individual has symptoms.[229] Although personal protective equipment (PPE) and other infection control- precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between HCP and patients or from patient to patient given the close contact that may occur during the provision of care.[230] The CDC has emphasized that health care settings, including long-term care (LTC) settings, can be high-risk places for COVID–19 exposure and transmission.[231]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[232] On December 11, 2020, the Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[233] Subsequently, FDA issued EUAs for additional COVID–19 vaccines.[234] [235] Following the publication of the proposed rule, FDA granted full approval to Comirnaty, the Pfizer-BioNTech COVID–19 vaccine on August 23, 2021 for individuals 16 years of age and older.[236]

As part of its national strategy to address COVID–19, the White House stated on March 25, 2021 that it would work with states and the private sector to execute an aggressive vaccination strategy and has outlined a goal of administering 200 million shots in 100 days.[237] On April 21, 2021, it was announced that this goal had been achieved.[238] Although the goal of the U.S. Government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, the Department of Health and Human Services (HHS), the Department of Defense (DoD), and the CDC, recommended that early vaccination efforts focus on those critical to the PHE response, including HCP, and individuals at highest risk for developing severe illness from COVID–19.[239] For example, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccination, given the potential for transmission in health care

[217] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[218] Centers for Disease Control and Prevention. (2020). Health Equity Considerations and Racial and Ethnic Minority Groups. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html*.

[219] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days*.

[220] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days*.

[221] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895*. Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html*.

[222] US Currently Hospitalized | The COVID Tracking Project. Accessed January 31, 2021 at: *https://covidtracking.com/data/charts/us-currently-hospitalized*.

[223] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[224] Centers for Disease Control and Prevention. (2021). Interim Public Health Recommendations for Fully Vaccinated People. Accessed on June 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html*.

[225] *Ibid.*

[226] *Ibid.*

[227] *Ibid.*

[228] Centers for Disease Control and Prevention. (2020). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[229] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html*.

[230] Centers for Disease Control and Prevention. 2021. Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission*.

[231] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[232] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[233] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144412/download*.

[234] U.S. Food and Drug Administration. (2021). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download*.

[235] U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download*.

[236] U.S. Food and Drug Administration. (2021). Comirnaty and Pfizer-BioNTech COVID–19 Vaccine. Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine*.

[237] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on April 3, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/*.

[238] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on June 2, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/21/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations-2/*.

[239] Health and Human Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf*; Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*. Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation.

settings and the need to preserve health care system capacity.[240] Research suggests most states followed this recommendation,[241] and HCP began receiving the vaccine in mid-December of 2020.[242]

Frontline healthcare workers, such as those employed in hospitals, have been prioritized for vaccination in most locations. There are approximately 18 million healthcare workers in the U.S.[243] A survey of HCP found that 66 percent of hospital HCP and 64 percent of outpatient clinic HCP reported receiving at least one dose of the vaccine.[244] As of July 2, 2021, the CDC reported that over 328 million doses of COVID–19 vaccine have been administered and approximately 155.9 million people were fully vaccinated.[245] Subsequently, the CDC reported that as of October 14, 2021, over 405 million doses of COVID–19 vaccine have been administered and approximately 188.3 million people had received full doses.[246] The White House indicated on April 6, 2021, that the U.S. retains sufficient vaccine supply, and every adult became eligible to receive the vaccine beginning April 19, 2021.[247] Finally, as part of the Biden Administration's efforts to vaccinate those who are still unvaccinated through increasing the number of Americans covered by vaccination requirements,[248] on September 9, 2021, the Biden Administration announced that COVID–19 vaccination will be required of all staff within Medicare and Medicaid-certified facilities to protect both patients and HCP against COVID–19.[249]

We believe it is important to require that hospital outpatient departments (HOPDs) report HCP vaccination information for health care facilities to assess whether these facilities are taking steps to limit the spread of COVID–19 among their health care workers and to help sustain the ability of HOPDs to continue serving their communities throughout the PHE and beyond. Therefore, we proposed to adopt a new measure, COVID–19 Vaccination Coverage Among HCP beginning with the CY 2024 payment determination. For that payment year, hospitals would be required to report data quarterly on the measure for the January 2022 through December 2022 reporting period. The measure would assess the proportion of a hospital's health care workforce that has been vaccinated against COVID–19.

HCP are at risk of transmitting COVID–19 infection to patients, experiencing illness or death as a result of COVID–19 themselves, and transmitting it to their families, friends, and the general public. We believe HOPDs should report the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. HCP vaccination can reduce illness that leads to work absence and limit disruptions to providing care [250] with major reductions in SARS–CoV–2 infections among those receiving two dose COVID–19 vaccine despite a high community infection rate.[251] Data from influenza vaccination demonstrates that provider vaccination is associated with that provider recommending vaccination to patients,[252] and we believe HCP COVID–19 vaccination in HOPDs could similarly increase uptake among that patient population. We also believe that publicly reporting the HCP vaccination rates would be helpful to many patients, including those who are at high risk-for developing serious complications from COVID–19, as they choose HOPDs for treatment. Under CMS' Meaningful Measures Framework, the COVID–19 measure addresses the quality priority of ''Promote Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

(2) Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure (''COVID–19 HCP vaccination measure'') is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in non-LTC facilities including outpatient hospitals.

(a) Measure Specifications

The denominator for the HCP measure is the number of HCP eligible to work in the hospital for at least 1 day during the self-selected week, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[253]

[240] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[241] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/*.

[242] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f*.

[243] Centers for Disease Control and Prevention. Healthcare Workers. (2017) Accessed February 18, 2021 at: *https://www.cdc.gov/niosh/topics/healthcare/default.html*.

[244] KFF/The Washington Post Frontline Health Care Workers Survey. (2021). Accessed June 2, 2021 at: *https://www.kff.org/coronavirus-covid-19/poll-finding/kff-washington-post-health-care-workers/*.

[245] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. COVID Data Tracker. COVID–19 Vaccinations in the United States. (2021). Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations*.

[246] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. (2021). COVID Data Tracker. COVID–19 Vaccinations in the United States. Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations*.

[247] The White House. Remarks by President Biden Marking the 150 Millionth COVID–19 Vaccine Shot. Accessed April 8, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/06/remarks-by-president-biden-marking-the-150-millionth-covid-19-vaccine-shot/*.

[248] The White House. Path Out of the Pandemic: President Biden's COVID–19 Action Plan. Accessed on October 14, 2021. Available at: *https://www.whitehouse.gov/covidplan/#vaccinate*.

[249] CMS. Press Release: Biden-Harris Administration to Expand Vaccination Requirements for Health Care Settings. September 9, 2021. Available at: *https://www.cms.gov/newsroom/press-releases/biden-harris-administration-expand-vaccination-requirements-health-care-settings*. In order to implement this plan, CMS is working with the CDC to develop an Interim Final Rule with Comment Period that will extend emergency regulations to require vaccination among staff in a wide range of healthcare settings including dialysis facilities. This action will create a consistent standard across the country, while giving patients assurance of the vaccination status of those delivering care.

[250] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm*.

[251] Benenson S, Oster Y, Cohen MJ, Nir-Paz R. BNT162b2 mRNA Covid–19 Vaccine Effectiveness among Health Care Workers. N Engl J Med. 2021. See also: Keehner J, Horton LE, Pfeffer MA, Longhurst CA, Schooley RT, Currier JS, et al. SARS–CoV–2 Infection after Vaccination in Health Care Workers in California. N Engl J Med. 2021.

[252] Measure Application Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[253] Centers for Disease Control and Prevention. Contraindications and precautions. (2021) Accessed March 15, 2021 at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications*.

The numerator for the HCP measure is the cumulative number of HCP eligible to work in at the hospital for at least 1 day during the self-selected week and who received a complete vaccination course against COVID–19.[254] [255] [256] [257] [258] A complete vaccination course is defined under the specific manufacturer and may require multiple doses or regular revaccination.[259] Vaccination coverage for purposes of this measure is defined as the estimated percentage (given the potential for week-to-week variation) of HCP eligible to work at the hospital for at least 1 day who received a COVID–19 vaccine. Acute care facilities would count HCP working in all inpatient or outpatient units that are physically attached to the inpatient acute care facility site and share the same CMS certification number (CCN), regardless of the size or type of unit. Facilities would also count HCP working in inpatient and outpatient departments that are affiliated with the specific acute care facility (such as sharing medical privileges or patients), regardless of distance from the acute care facility and also share the same CCN. The decision to include or exclude HCP from the acute care facility's HCP vaccination counts would be based on whether individuals meet the specified National Healthcare Safety Network (NHSN) criteria and are physically working in a location that is considered any part of the on-site acute care facility that is being monitored.[260] The proposed specifications for the COVID–19 vaccination coverage among HCP measure are available on the NQF website at: *https://www.cdc.gov/nhsn/nqf/index.html*.

(b) Review by the Measure Applications Partnership

The COVID–19 HCP vaccination measure was included on the publicly available ''List of Measures Under Consideration for December 21, 2020,'' [261] a list of measures under consideration for use in various Medicare programs. The Measure Applications Partnership (MAP) hospital workgroup convened on January 11, 2021, and it reviewed the list of Measures Under Consideration (MUC) including the COVID–19 HCP vaccination measure. The MAP hospital workgroup agreed that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it could bring value to the Hospital OQR Program measure set by providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[262] The MAP hospital workgroup also stated in its preliminary recommendations that collecting information on COVID–19 vaccination coverage among HCP and providing feedback to hospitals would allow hospitals to benchmark coverage rates and improve coverage in their facility, and that reducing COVID–19 infection rates in HCP may reduce transmission among patients and reduce instances of staff shortages due to illness.[263]

In its preliminary recommendations, the MAP hospital workgroup did not support this measure for rulemaking, subject to the potential for mitigation.[264] To mitigate its concerns, the MAP hospital workgroup believed that the measure needed well-documented evidence, finalized specifications, testing, and National Quality Forum (NQF) endorsement prior to implementation.[265] Subsequently, the MAP Coordinating Committee met on January 25, 2021, and reviewed the COVID–19 HCP vaccination measure. In its 2020–2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measure back to the MAP once the specifications were further refined. The MAP specifically stated, ''the incomplete specifications require immediate mitigation and further development should continue.'' [266] In its final report, the MAP noted that the measure would add value by providing visibility into an important intervention to limit COVID–19 infections in HCP and the patients for whom they provide care.[267] The spreadsheet of final recommendations no longer cited concerns regarding evidence, testing, or NQF endorsement.[268] In response to the MAP final recommendation request that CMS bring the measure back to the MAP once the specifications are further refined, CMS and the CDC met with the MAP Coordinating Committee on March 15, 2021. Additional information was provided to address vaccine availability, alignment of the COVID–19 HCP vaccination measure as closely as possible with the data collection for the Influenza HCP vaccination measure (NQF #0431), and clarification related to how HCP are defined. CMS and the CDC also presented preliminary findings from the testing of the numerator of the COVID–19 HCP vaccination measure, which was in process. These preliminary findings showed numerator data should be feasible to collect and reliable. Testing of the measure numerator (the number of HCP vaccinated) involved a comparison of the data collected through the NHSN and independently reported through the Federal pharmacy partnership program for delivering vaccination to LTC facilities. These are two completely independent data collection systems. In initial analyses of the first month of vaccination, the number of healthcare workers vaccinated in approximately 1,200 facilities for which data from both systems was available, the number of healthcare personnel vaccinated was highly correlated between the two systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting.[269] Because of the high correlation across a large number of facilities and high number of HCP within those facilities receiving at least one dose of the COVID–19 vaccine, we believe the measure is feasible and

[254] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[255] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[256] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage Updated August 2021. Available at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf*.

[257] National Health Safety Network. Healthcare Personnel COVID–19 Vaccination Cumulative Summary (CDC 57.219, Rev 5). Updated September 2021. Available at: *https://www.cdc.gov/nhsn/forms/57.219-p.pdf*.

[258] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html#:~:text=If%20you%20have%20received%20all,to%20be%20fully%20vaccinated*.

[259] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[260] Centers for Disease Control and Prevention. CMS Reporting Requirements FAQs. Accessed June 2, 2021 at: *https://www.cdc.gov/nhsn/PDFs/CMS/faq/FAQs-CMS-Reporting-Requirements.pdf*.

[261] The National Quality Forum. (2021) Accessed March 14, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212*.

[262] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

[263] *Ibid.*

[264] *Ibid.*

[265] *Ibid.*

[266] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

[267] *Ibid.*

[268] *Ibid.*

[269] For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

reliable for use in HOPDs. After reviewing this additional information, the MAP retained its final recommendation of conditional support, and expressed support for CMS' efforts to use the measure as part of the solution for the COVID–19 public health crisis.[270]

Section 1890A(a)(4) of the Act, as added by section 3014(b) of the Affordable Care Act, requires the Secretary to take into consideration input from multi-stakeholder groups in selecting certain quality and efficiency measures. While we value input from the MAP, we believe it is important to propose the measure as quickly as possible to address the urgency of the COVID–19 PHE and its impact on high risk populations, including hospitals. CMS continues to engage with the MAP to mitigate concerns and appreciates the MAP's conditional support for the measure.

(c) Measure Endorsement

Under section 1833(t)(17)(C)(i) of the Act, unless the exception of subclause (ii) applies, measures selected for the Hospital OQR Program must have been set forth by the entity with a contract under section 1890(a) of the Act. The NQF currently holds this contract. Under section 1833(t)(17)(C)(ii) of the Act, the Secretary shall develop measures that the Secretary determines to be appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, as we have noted in previous rulemaking (for example, 75 FR 72065 and 76 FR 74494 for the Hospital OQR and ASCQR Programs, respectively), the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

The COVID–19 HCP vaccination measure is not NQF-endorsed; however, the CDC submitted the measure for consideration in the NQF Fall 2021 measure cycle.

Because this measure is not NQF-endorsed, we considered whether there are other available measures that assess COVID–19 vaccination rates among HCP. We found no other feasible and practical measures on the topic of COVID–19 vaccination among HCP.

(d) Data Collection, Submission, and Reporting

Given the time sensitive nature of this measure considering the current PHE, we proposed that hospitals would be required to begin reporting data on the COVID–19 HCP vaccination measure (OP–38) beginning January 1, 2022, for the CY 2024 payment determination for the Hospital OQR Program. Thereafter, we proposed quarterly reporting periods. While we considered annual reporting periods for the Hospital OQR Program, we proposed quarterly reporting periods given the immediacy of the PHE and the importance of alignment across quality payment programs that have since finalized this measure.

In the CY 2022 OPPS/ASC proposed rule (86 FR 42241), we stated that if our proposal to adopt this measure is finalized, hospitals would report the measure through the CDC's NHSN web-based surveillance system.[271] While the Hospital OQR Program does not currently require use of the NHSN web-based surveillance system, we have previously required use of this system for submitting data. We refer readers to the CY 2014 OPPS/ASC final rule with comment period in which we adopted the Influenza Vaccination Coverage Among Health Care Personnel (NQF #0431) measure (OP–38) (78 FR 75096 through 75099), section XV.D.5.b.(1) of the CY 2022 OPPS/ASC proposed rule (86 FR 42259), and this final rule for additional information on reporting through the NHSN web-based surveillance system under the Hospital OQR Program. Hospitals also have experience reporting acute care hospital measures to the CDC's NHSN under the Hospital IQR Program.

To report this measure, we proposed that hospitals would collect the numerator and denominator for the COVID–19 HCP vaccination measure for at least one, self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet Hospital OQR Program requirements. While we believe that it would be ideal to have HCP vaccination data for every week of each month, we are mindful of the time and resources that hospitals would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable snapshot of vaccination levels among a hospital's HCP while balancing the costs of reporting. If a hospital submits more than one week of data in a month, the most recent week's data would be used to calculate the measure. For example, if first and third week data are submitted, the third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. For each quarter, we proposed that the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each hospital, which would be calculated by taking the average of the data from the three submission periods submitted by the hospital for that quarter. If finalized, CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

Hospitals would submit the number of HCP eligible to have worked at the facility during the self-selected week that the hospital reports data in NHSN (denominator) and the number of those HCP who have received a complete course of a COVID–19 vaccination (numerator) during the same self-selected week. As previously stated, acute care facilities would count HCP working in all inpatient or outpatient units that share the same CCN, regardless of the size or type of unit.[272]

We received comments on these topics.

Comment: Many commenters supported our proposal to adopt the COVID19 Vaccination Coverage Among HCP Measure and expressed the importance of vaccination in the fight against COVID–19. Several commenters noted that their facilities have already implemented COVID–19 vaccination requirements and that the measure bolsters their efforts to promote vaccination among HCP. Some commenters stated that, given the surge of the Delta variant, the implementation of this measure should not be delayed as widespread vaccination is critical to prevent the spread and further variants of COVID–19. Other commenters noted that the measure has already been approved in other Medicare quality reporting programs and its inclusion in outpatient programs is appropriate and consistent. Some commenters also stated that reporting the measure will ensure transparency and accountability in infection prevention and control for

[270] *Ibid.*

[271] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

[272] *Ibid.*

vulnerable populations and communities. Still other commenters appreciated that the measure would make COVID–19 vaccination information available to the public to make informed health care decisions.

Response: We thank commenters for their support of the measure and agree that the measure is critically important in the ongoing fight against COVID–19.

Comment: Several commenters expressed concern that COVID–19 vaccines are authorized under EUA and the measure should not be adopted until such time that a vaccine has received full FDA approval. One commenter stated that all three currently available vaccinations should be fully approved by FDA prior to adoption of this measure because the commenter believes that this will reduce vaccine hesitancy.

Response: On August 23, 2021, subsequent to the publication of the CY 2022 OPPS/ASC proposed rule (86 FR 42240), FDA granted full approval to Comirnaty, formerly known as the Pfizer-BioNTech COVID–19 vaccine.[273] While we recognize that there are differences between EUA authorization and full FDA approval, we note that the process for each is scientifically rigorous. We refer readers to information related to FDA's process for evaluating an Emergency Use Authorization (EUA) request at *https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained*.[274] Each vaccine manufacturer that received EUA authorization enrolled tens of thousands of participants in randomized clinical trials, which is similar to what is required for full FDA approval.[275] Manufacturers submit robust and rigorous data for both an EUA authorization and full FDA approval, and more than 380 million doses of COVID–19 vaccines have been administered.[276] We believe all COVID–19 vaccines with either full approval or EUA authorization to be proven safe and effective. Thus, we believe it is appropriate to include the measure in the Hospital OQR Program.

We further note that the COVID–19 Vaccination Coverage Among HCP measure does not itself require HCP to receive the vaccination, nor does this measure reward or penalize HOPDs for the rate of HCP who have received a COVID–19 vaccine. The COVID–19 Vaccination Coverage Among HCP measure requires HOPDs to collect and report COVID–19 vaccination data that would support public health tracking and provide beneficiaries and their caregivers information to support informed decision making.

Comment: Several commenters expressed concern that this measure should not be adopted until there is clarity around the impact of future booster recommendations. One commenter stated that the numerator requirement of a completed vaccination course may change over time and recommended that CMS establish a definition of completed vaccination course using the national guidelines as of the date the OPPS Final Rule is published each year. Some commenters noted that supply disruptions could have an impact on vaccination coverage among HCP. Some commenters observed that tracking whether HCP have received a complete vaccination course when there are individual differences regarding what is considered a complete vaccination course increases reporting burden. Another commenter questioned how COVID–19 vaccinations will be financed in the future, and whether HCP will be required to pay out of pocket for vaccines and boosters which could impact the numerator requirement for the measure and lead HCP to decline future required doses of the vaccine. Other commenters recommended that reporting for the measure should be optional or delayed until a completed vaccination course can be more clearly and specifically defined. Several commenters recommended that CMS issue guidance on how the measure addresses boosters after booster recommendations have been issued by FDA and the CDC.

Response: The COVID–19 Vaccination Coverage Among HCP measure is a measure of a completed vaccination course (as defined in section XV.B.4.a.2. of the CY 2022 OPPS/ASC proposed rule (86 FR 42240)) and does not address booster shots. On August 12, 2021, FDA amended the emergency use authorizations (EUAs) for both the Pfizer-BioNTech COVID–19 Vaccine and the Moderna COVID–19 Vaccine to allow for the use of an additional dose in certain immunocompromised individuals, specifically, solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.[277] The Centers for Disease Control on September 27, 2021 further recommended Pfizer-BioNTech boosters for individuals who completed their initial series at least six months ago and are 65 years of age or older; 18 years of age or older with underlying medical conditions; and 18 years of age or older living and working in high-risk settings, which includes healthcare workers.[278] We acknowledge commenter concerns that hospitals may be required to collect additional information from HCP on booster doses. However, we believe that the numerator is sufficiently broad to include future boosters as part of a ''complete vaccination course''.

Comment: A few commenters expressed concern about the burden of accurately capturing the number of eligible HCP in the facility for the measure specifications and believed that the total population intended to be captured in the denominator is unclear. Some of these commenters further noted that capturing data such as contraindications would further increase the burden. Commenters further requested CMS clarify the measure specifications of the denominator.

One commenter discussed the challenge for systems or facilities with multiple locations that share the same CCN, facilities located on the same physical site that do not share the same CCN, or systems with many HCP that provide care in more than one setting during a calendar year including physicians who provide most of their services at an outpatient hospital or facility but also provide inpatient care for a few days per year. The commenter stated that in the example of a HCP who primarily practices at an outpatient hospital, but sometimes provides inpatient care, a review of charge-level details for each provider would be necessary to determine if the physicians provided services at the hospital during a specific reporting period, which would be burdensome. The commenter further discussed their system's policy to require vaccination of all HCP as a

[273] U.S. Food and Drug Administration. Comirnaty and Pfizer-BioNTech COVID–19 Vaccine. August 30, 2021. Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine*.

[274] At *https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained*.

[275] Harvard Law Petrie-Flom Center. ''What's the Difference Between Vaccine Approval (BLA) and Authorization (EUA)?'' June 15, 2021. Available at: *https://blog.petrieflom.law.harvard.edu/2021/06/15/whats-the-difference-between-vaccine-approval-bla-and-authorization-eua/*.

[276] Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker: COVID–19 Vaccinations in the United States. Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations*.

[277] U.S. Food and Drug Administration. Coronavirus (COVID–19) Update: FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals. August 12, 2021. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised*.

[278] Ibid.

condition of employment and noted that this alternative approach was more administratively feasible than the proposed measure specifications. To alleviate the challenge of collecting the denominator of eligible HCP working in the facility during the reporting period, the commenter requested CMS define ''eligible'' HCP and further recommended that CMS offer an attestation alternative for reporting by which an institution would receive 100 percent compliance for the measure if the institution attests that there is a COVID–19 Vaccine Policy which requires that all current employees, students, residents, volunteers, and contractors be fully vaccinated on or before December 31, 2021, and furthermore requires that all new employees receive their first COVID–19 vaccination before starting work and the new employee must be fully vaccinated within 60 days of the hire date. If an institution does not have a policy that meets these criteria, the commenter suggested the institution would be required to report the numerator and denominator as specified in the proposed measure. One commenter requested clarification of whether reporting data for IQR meets the requirements to report for the OQR program.

Response: We recognize commenters' concerns regarding reporting burden associated with the specifications of this measure specifically around the definition of HCP. We note that given the highly infectious nature of the COVID–19 virus, we believe it is important to encourage all personnel within the hospital, regardless of patient contact, role, or employment type, to receive the COVID–19 vaccination to prevent outbreaks within the hospital which may affect resource availability and have a negative impact on patient access to care.

We also note that the measure specifications define ''eligible'' HCP as all persons receiving a direct paycheck from the reporting facility (that is, on the facility's payroll), regardless of clinical responsibility or patient contact, licensed independent practitioners, and adult students, trainees and volunteers.[279] CDC's guidance for entering data requires submission of HCP count at the facility level,[280] and the measure requires reporting consistent with that guidance. Hospitals should count HCP working in all inpatient or outpatient units that are physically attached to the inpatient site and share the same CCN, regardless of the size or type of unit.[281] Hospitals should also count HCP working in inpatient and outpatient departments that are affiliated with the specific hospital (such as sharing medical privileges or patients), regardless of distance from the hospital and also share the same CCN.[282] The decision to include or exclude HCP from the hospital's HCP vaccination counts should be based on whether individuals meet the specified NHSN criteria and are physically working in a location that is considered any part of the on-site hospital that is being monitored.[283]

The CDC has provided a number of resources including a tool called the Data Tracking Worksheet for COVID–19 Vaccination among Healthcare Personnel to help hospitals log and track the number of HCP who are vaccinated for COVID–19. Hospitals would enter COVID–19 vaccination data for each HCP in the tracking worksheet, and select a reporting week, and the data to be entered into the NHSN will automatically be calculated on the Reporting Summary.[284] Using the CDC Data Tracking Worksheet and Reporting Summary, hospitals would only be required to report information once to capture inpatient and outpatient HCP as long as the HCP included in the report work at facilities that share the same CCN. Therefore, hospitals would be required to submit once for both the Hospital IQR and Hospital OQR Programs so long as the HCP included in the report work at facilities that share the same CCN. If HCP work at multiple facilities that do not share the same CCN, those individuals must be counted under each facility's CCN where they work during the week of data collection.[285]

Comment: A few commenters noted that, while vaccination plays an important role in ending the COVID–19 pandemic, the measure is not currently endorsed by the National Quality Forum and they believed it should not be adopted until it receives such an endorsement. One commenter observed that NQF endorsement improves credibility and affords patients certainty that the measure data is reliable. One commenter recommended that CMS clarify that the adoption of a measure prior to NQF endorsement is only due to the exigency of the current circumstances.

Response: We believe that in the context of the current COVID–19 PHE and continued monitoring and surveillance following the PHE, it is important to adopt this measure as quickly as possible to allow tracking and reporting of COVID–19 Vaccination Coverage Among HCP. This tracking would allow hospitals to identify the appropriateness and effectiveness of their initiatives to improve vaccination coverage and would provide patients and consumers with important information. We therefore believe it is appropriate to use our authority pursuant to section 1833(t)(17)(C)(i) of the Act to develop this measure. That provision permits the Secretary to develop measures that the Secretary determines to be appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measure set forth by one or more national consensus building entities. As described above, we believe that consensus among affected parties regarding a measure can be achieved through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

Here, we note our efforts to build consensus regarding this measure through our coordination with the CDC, the use of this measure across quality programs, and the pressing need to better track and report COVID–19 vaccination coverage among HCP. There is no National Quality Forum endorsed measure on the topic of COVID–19 vaccination coverage among healthcare personnel, let alone any such measure that is feasible or practical for CMS to implement. We also note that the CDC has submitted this measure for consideration in the NQF Fall 2021 measure cycle.

Separately, we believe that the Secretary's selection of this measure is additionally supported by section 1833(t)(17)(C)(ii) of the Act, which permits the Secretary to select measures that are the same as (or a subset of) the measure for which data are required to

[279] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage Updated August 2021. Available at: COVID–19 Vaccination of Healthcare Personnel Measure Specifications (*cdc.gov*).

[280] COVID–19 Vaccination Non-LTC Healthcare Personnel TOI (*cdc.gov*).

[281] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage. Available at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vaxhcpcoverage-508.pdf.*

[282] Ibid.

[283] Centers for Disease Control and Prevention. CMS Reporting Requirements FAQs. Available at: *https://www.cdc.gov/nhsn/PDFs/CMS/faq/FAQs-CMS-Reporting-Requirements.pdf.*

[284] Data Tracking Worksheet for COVID–19 Vaccination among Healthcare Personnel at *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html.*

[285] Centers for Disease Control and Prevention. FAQs on Reporting COVID–19 Vaccination Data. August 2021. Available at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/faqs.html.*

be submitted under the Hospital Inpatient Quality Reporting (IQR) Program. The Hospital IQR Program recently adopted the COVID–19 Vaccination Coverage Among HCP measure (86 FR 45382).

Comment: One commenter recommended that CMS monitor for unintended consequences associated with the COVID–19 Vaccination Coverage Among HCP measure due to its short development and adoption timeline.

Response: We appreciate the commenter's suggestion. As previously stated, the COVID–19 vaccines have received rigorous scientific review and FDA has determined that the known and potential benefits outweigh the known and potential risks. Additionally, as the measure steward, the CDC continuously monitors reporting of COVID–19 vaccination data via the NHSN to improve infection control and help target facility-level improvement efforts.[286]

We acknowledge the commenter's concern regarding the development timeline of COVID–19 vaccines. However, as stated previously, we believe all authorized COVID–19 vaccines to be proven safe and effective and believe it is appropriate to include the measure in the Hospital OQR Program.

Comment: A few commenters supported the use of NHSN to report measure data and noted that reporting via NHSN is likely to reduce burden for hospitals.

Response: We thank the commenters for their support.

Comment: Several commenters cited Equal Employment Opportunity Commission (EEOC) guidelines, which state that employers must provide a reasonable accommodation if an employee's sincerely held religious belief, practice, or observance prevents them from receiving the vaccination. The commenters requested CMS and the CDC to revise the measure exclusions to align with EEOC guidance.

Response: We recognize that there are reasons, including religious objections or concerns regarding an individual provider's specific health status, that may lead an individual HCP to decline vaccination. We emphasize that this measure does not mandate vaccines; it only requires reporting of vaccination rates for successful program participation. However, we believe that accurate vaccination rates of HCP are meaningful data for patients and beneficiaries to use when choosing a hospital. The CDC, the measure's steward, offers guidance to hospitals that may decide to report HCP who decline vaccination due to religious reasons.[287] Those HCP, however, would be included in the measure denominator along with other HCP who have not received a completed vaccination course.[288] We further note that the Equal Employment Opportunity Commission (EEOC) released updated and expanded technical assistance on May 28, 2021, stating that Federal equal employment opportunity (EEO) laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID–19, so long as the employer complies with the reasonable accommodation provisions of the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 and other EEOC considerations.[289] In summary, we do not believe that this measure conflicts with any EEOC guidance and believe that it is appropriate to require hospitals to report these data.

Comment: A few commenters stated that they do not believe the measure is appropriate for quality reporting programs at this time. One commenter stated that the COVID–19 Vaccination Coverage Among HCP measure is dissimilar to the Influenza Vaccination Coverage Among HCP (NQF #0431) measure and the discrepancy between time and resources required for reporting renders the proposed COVID–19 Vaccination Coverage Among HCP measure inappropriate for hospitals at this time. Another commenter stated that the COVID–19 pandemic is ongoing, and the evolving nature of the vaccination effort indicates the measure is not yet mature enough for inclusion in the program. Another commenter observed that it is inappropriate to base this measure on the influenza vaccination measure due to the lack of evidence that COVID vaccines and influenza vaccines are clinically similar.

Response: We thank the commenters for their feedback. We acknowledge that while the CDC, the measure's steward, has sought to align this measure with the Influenza Vaccination Coverage Among HCP measure (NQF #0431), these are different public health initiatives, and different vaccines, and therefore the measure specifications are not in complete alignment. For example, influenza is seasonal while SARS–CoV–2 has circulated continuously since the first cases were reported in the U.S. in January 2020.

With regard to commenters stating that it is premature to adopt the measure, we believe that COVID–19 vaccines are a crucial tool for slowing the spread of disease and death among patients, hospital staff, and the general public. Based on FDA's review, evaluation of the data, and its decision to authorize three vaccines for emergency use and to provide full approval to one vaccine, these vaccines meet FDA's applicable standards for safety and effectiveness to prevent COVID–19, including hospitalization and death.[290] The combination of vaccination, universal source control (that is, wearing masks), social distancing, and handwashing offers further protection from COVID–19.[291] Since the publication of the proposed rule, the emergence of coronavirus variants have resulted in 8.9 million new virus cases.[292] Given the EUA and full approval decisions by FDA and the continued PHE, we do not believe that adoption of the measure is premature. We believe our proposal to adopt the COVID–19 Vaccination Coverage among HCP measure to the Hospital OQR Program is appropriate and necessary for patient safety and to better inform patient decision-making.

Comment: Some commenters stated that it is inappropriate to use payment policies to drive vaccination coverage among HCP. Some commenters expressed concern that this measure could lead facilities to mandate vaccines for staff, with potential unintended consequences (specifically, staff quitting or legal risk for facilities for staff experiencing adverse events).

Response: We thank commenters for their feedback and. understand their

[286] Ibid.

[287] Centers for Disease Control and Prevention. Reporting Weekly COVID–19 Vaccination Data for Healthcare Personnel Using the National Healthcare Safety Network (NHSN). September 2021. Available at: *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/weekly-covid-reporting-508.pdf.*

[288] Centers for Disease Control and Prevention. Reporting Weekly COVID–19 Vaccination Data for Healthcare Personnel Using the National Healthcare Safety Network (NHSN). September 2021. Available at: *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/weekly-covid-reporting-508.pdf.*

[289] U.S. Equal Employment Opportunity Commission. What You Should Know About COVID–19 and the ADA, the Rehabilitation Act, and Other EEO Laws. May 28, 2021. Available at: *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.*

[290] U.S. Food and Drug Administration. COVID–19 Vaccines. (2021). Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.*

[291] Centers for Disease Control and Prevention. How to Protect Yourself & Others. August 13, 2021. Available at *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.*

[292] Centers for Disease Control and Prevention. Trends in Number of COVID–19 Cases and Deaths in the US Reported to CDC. Accessed September 22, 2021. Available at: *https://covid.cdc.gov/covid-data-tracker/#trends_totalcases.*

concerns. We emphasize that this measure does not require a hospitals to enforce staff vaccination in order for the hospital to successfully participate in the Hospital OQR Program; instead, the hospital must report the rate of its staff that have completed a complete vaccination course.

We noted in the CY 2022 OPPS/ASC proposed rule (86 FR 42239) that a survey of HCP from April 2021 found that 66 percent of hospital HCP and 64 percent of outpatient department HCP reported receiving at least one dose of the vaccine.[293] Subsequent to the publication of the CY 2022 OPPS/ASC proposed rule, research from August 2021 suggests that nearly 73 percent of HCP across all health care facilities have received at least one dose of the vaccine.[294] Based on the findings, we understand that HCP have been receiving the COVID–19 vaccine prior to the adoption of this measure and we do not believe that there is a negative relationship between vaccine uptake among HCP and vaccine requirements. We further emphasize the importance of HCP vaccination to reduce transmission of COVID–19 among hospital staff and patients, and we believe the measure is appropriate for inclusion in the Hospital OQR program.

Comment: Many commenters expressed concern that the measure reporting requirements are duplicative of other state and federal COVID–19 vaccination reporting requirements and that inclusion of the measure in quality reporting programs is unnecessarily burdensome for hospitals. Some commenters questioned the purpose of the measure given the CMS announcement on September 9, 2021 that the agency will require COVID–19 vaccination of staff within all Medicare and Medicaid-certified facilities.[295] Other commenters noted that they are currently required to report COVID–19 vaccination information to HHS and requested that such reporting might be considered a substitute to reporting proposed for the measure. A few commenters recommended a change to attestation-based reporting to reduce resources and burden required for reporting based on the proposed measure specifications. One commenter observed that time spent on multiple reporting requirements would take away from time available for efforts to improve vaccination coverage. Another commenter requested an analysis of burden and feasibility of data collection prior to adoption of the measure.

Response: We appreciate commenters' feedback. We note that most Immunization Information Systems do not include the information needed to determine if an immunized person is a resident of a nursing home, a dialysis patient, or a healthcare worker. Using the NHSN COVID–19 Vaccination Modules allows tracking vaccination coverage among the residents, patients, or healthcare personnel in your facilities.[296] We do recognize that this measure may lead to duplicative reporting if hospitals voluntarily report COVID–19 HCP vaccination information to other data reporting systems in addition to this measure requirement via the NHSN, and we are collaborating with other HHS agencies, including the CDC to minimize reporting burden to the extent feasible. We believe that the COVID–19 vaccination of HCP information submitted for this measure is important as it will be made publicly available for use by Medicare beneficiaries and others in making informed decisions regarding their care including facility choice.

With regard to measure burden analysis, we refer the commenter to section XXII.B.3.a. of this final rule with comment period, where we discuss the burden associated with the measure. We thank the commenters for the suggestion that the measure be attestation-based and note that any changes to the measure specifications would be proposed through future rulemaking.

Comment: A few commenters recommended that CMS reduce reporting frequency from quarterly to twice-yearly or annually to limit reporting burden. One characterized the reporting requirements to be weekly and recommended less frequent reporting requirements. Another commenter stated that the measure is duplicative with other requirements from the CDC and recommended that CMS not adopt the measure but instead collect the information directly from the CDC. Another commenter observed that there are not likely to be large changes in performance at quarterly intervals and recommended less frequent reporting.

Response: As stated in the CY 2022 OPPS/ASC proposed rule (86 FR 42270), we believe that it would be ideal to have HCP vaccination data for every week of each month, we are mindful of the time and resources that some facilities would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable estimate of vaccination levels among an ASC's HCP while balancing the costs of reporting. We believe that reporting at a lower frequency may result in data that is less meaningful and timely to consumers who want to consider HCP vaccination rates as part of their health care decision-making process. As stated previously, we are collaborating with other HHS agencies, including the CDC to minimize reporting duplication to the extent feasible.

Comment: One commenter recommended development of a validation process for the COVID–19 Vaccination Coverage Among HCP measure.

Response: We thank the commenter for the suggestion and note that, as stated in the CY 2022 OPPS/ASC proposed rule (86 FR 42241), the measure has been tested and shown to be feasible and reliable.

Comment: One commenter supported public reporting of this measure, and specifically noted support for early publication through the initial shortened reporting period.

Response: We thank the commenter for its support.

Comment: A few commenters did not support publicly reporting the measure data. One commenter stated that, all HCP should be vaccinated; however, reporting this information for payment purposes could create incentives for hospital employers to coerce and intimidate HCP who decline the vaccine. Some commenters recommended providing confidential feedback reports to hospitals instead of publicly reporting the data. One commenter recommended delaying public reporting until the underlying evidence is stable and hospitals have had opportunity to report data for several years.

Response: We thank commenters for their feedback. We believe that HCP vaccination is important to prevent the spread of COVID–19 and encourage HCP to disclose their vaccination status to facilitate reporting of the measure. We

[293] KFF/The Washington Post Frontline Health Care Workers Survey. (2021). Available at: *https://www.kff.org/coronavirus-covid-19/pollfinding/kff-washington-post-health-care-workers/.*

[294] Lazer, D. et al. The Covic States Project: A 50–State Covid–19 Survey Report #62: Covid–19 Vaccine Attitudes Among Healthcare Workers. Northeastern University, Harvard University, Rutgers University, and Northwestern University. August 16, 2021. Available at: *http://news.northeastern.edu/uploads/COVID19%20CONSORTIUM%20REPORT%2062%20HCW%20August%202021.pdf.*

[295] Centers for Medicare & Medicaid Services. Biden-Harris Administration to Expand Vaccination Requirements for Health Care Settings. September 9, 2021. Available at: *https://www.cms.gov/newsroom/press-releases/biden-harris-administration-expand-vaccination-requirements-health-care-settings.*

[296] Centers for Disease Control and Prevention. FAQs on Reporting COVID–19 Vaccination Data. August 2021. Available at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/faqs.html.*

do not believe public reporting of vaccination data will incentivize coercion or intimidation on the part of hospitals. We noted previously in this section as well as in the CY 2022 OPPS/ASC proposed rule (86 FR 42239), a survey of HCP from April 2021 found that 66 percent of hospital HCP and 64 percent of outpatient department HCP reported receiving at least one dose of the vaccine. Subsequent to the publication of the CY 2022 OPPS/ASC proposed rule, research from August 2021 suggests that nearly 73 percent of HCP across all health care facilities have received at least one dose of the vaccine.[297] Based on this data, we understand that HCP have been receiving the COVID–19 vaccine prior to the adoption of this measure and do not believe that this represents performance that suggests negative relationship between vaccine uptake among HCP and employer vaccination requirements. We believe that publicly reporting the data will be useful to consumers in choosing healthcare providers, including by making comparisons between hospitals.

Comment: One commenter recommended aligning with the policy finalized in the FY 2022 IPPS/LTCH PPS final rule in which only the most recent quarter of data will be used for public reporting (as opposed to a rolling 12-month report).

Response: We agree with the commenter and note that, in alignment with the FY 2022 IPPS/LTCH PPS final rule (86 FR 45382), we will not finalize our plan to add one additional quarter of data during each advancing refresh, until the point that four full quarters of data is reached and then report the measure using four rolling quarters of data. Instead, we will only report the most recent quarter of data. This would result in more meaningful information that is up to date and not diluted with older data. We emphasize that this modification of our proposal does not affect the data collection schedule established for submitting data to NHSN for the COVID–19 vaccination measure. This would simply update the data that are displayed for the public reporting purposes.

After consideration of the public comments we received, we are finalizing our proposal to adopt the COVID–19 Vaccination Coverage Among HCP measure (Newly designated as OP–38) with modification to the quarterly reporting deadlines beginning with the CY 2022 reporting period/CY 2024 payment determination and subsequent years. Based on the comments we have received, it is our belief that reporting a single HCP count for each healthcare facility enrolled in NHSN would reduce burden. Therefore, in collaboration with the CDC, facilities will report data to NHSN by enrolled facility (also known as OrgID). Similar to the data submission process used previously for the Influenza Vaccination Coverage Among Healthcare Personnel (OP–27) (79 FR 66945), the CDC will then translate and submit the data to CMS on behalf of the facilities by CCN.

Additionally, in order to reduce reporting burden, we are finalizing our proposal that facilities must count HCP working in all inpatient or outpatient units that are physically attached to the inpatient site and share the same CCN, regardless of the size or type of unit.[298] Facilities must also count HCP working in inpatient and outpatient departments that are affiliated with the specific hospital (such as sharing medical privileges or patients), regardless of distance from the hospital and also share the same CCN. Reporting data in this way will allow healthcare facilities with multiple care settings to simplify data collection and submit a single count applicable across the inpatient and outpatient settings. We will then publicly report the percentage of HCP who received a complete course of the COVID–19 vaccination per CCN. This single HCP count per CCN will inform the public of the percentage of vaccinated HCP at a particular healthcare facility, which will provide meaningful data and help to improve the quality of care while reducing the burden of reporting.

We are also finalizing our proposal to publicly report the measure, which will begin with the October 2022 Care Compare refresh, or as soon as technically feasible, using data collected from Q1 2022 (January 1, 2022 through March 31, 2022). However, based on public comment, we are finalizing a modification to our proposal. We will not finalize our plan to add one additional quarter of data during each advancing refresh, until the point that four full quarters of data is reached and then report the measure using four rolling quarters of data. Instead, we will only report the most recent quarter of data. This would result in more meaningful information that is up to date and not diluted with older data.

b. Adoption of the Breast Cancer Screening Recall Rates Measure Beginning With the CY 2023 Payment Determination

(1) Background

Performing breast imaging in the outpatient setting facilitates early detection of malignancies.[299] However, performing diagnostic mammography or digital breast tomosynthesis (DBT) as a result of a false-positive screening study or other errant data has the potential to expose women to unnecessary follow-up.[300] This could result in increased prevalence of radiation-induced cancers in younger individuals including those carrying related gene mutations, such as BRCA–1 and BRCA–2 [301] [302] or additional imaging and biopsies, which could lead to unnecessary procedures for individuals who do not have breast cancer.[303] [304] In contrast, recalling too few women for follow-up imaging may lead to delayed diagnoses, higher stages at diagnosis, and/or undetected cases of breast cancer.[305] Given the potential

[297] Lazer, D. et al. The COVID States Project: A 50-state COVID–19 Survey Report #62: COVID–19 Vaccine Attitudes Among Healthcare Workers. Northeastern University, Harvard University, Rutgers University and Northwestern University. August 16, 2021. Available at: *http://news.northeastern.edu/uploads/COVID19%20CONSORTIUM%20REPORT%2062%20HCW%20August%202021.pdf.*

[298] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage. Available at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.*

[299] Coleman, C. (2017). Early detection and screening for breast cancer. Seminars in Oncology Nursing, 33(2), 141–155. *http://dx.doi.org/10.1016/j.soncn.2017.02.009.*

[300] Bernardi D., Li T., Pellegrini M., Macaskill, P., Valentini, M., Fanto, C., Ostillo, L., & Houssami, N. (2018). Effect of integrating digital breast tomosynthesis (3D-mammography) with acquired or synthetic 2D-mammography on radiologists' true positive and false-positive detection in a population screening trial: A descriptive study. European Journal of Radiology, 106, 26–31.

[301] Berrington de Gonzalez, A., Berg, C.D., Visvanathan, K., & Robson, M. (2009). Estimated risk of radiation-induced breast cancer from mammographic screening for young BRCA mutation carriers. Journal of the National Cancer Institute, 101(3), 205–209. *https://doi.org/10.1093/jnci/djn440.*

[302] Miglioretti, D.L., Lange, J., van den Broek, J.J., Lee, C.I., van Ravesteyn, N.T., Ritley, D., Kerlikowske, K., Fenton, J.J., Melnikow, J., de Koning, H.J., & Hubbard, R.A. (2016). Radiation-induced breast cancer incidence and mortality from digital mammography screening: A modeling study. Annals of internal medicine, 164(4), 205–214. *https://doi.org/10.7326/M15-1241.*

[303] Long, H., Brooks, J.M., Harvie, M., Maxwell, A., & French, D.P. (2019). How do women experience a false-positive test result from breast screening? A systematic review and thematic synthesis of qualitative studies. British journal of cancer, 121(4), 351–358. *https://doi.org/10.1038/s41416-019-0524-4.*

[304] Nelson, H.D., Pappas, M., Cantor, A., Griffin, J., Daeges, M., & Humphrey, L. (2016). Harms of breast cancer screening: systematic review to update the 2009 U.S. preventive services task force recommendation. *Annals of internal medicine, 164*(4), 256–267. *https://doi.org/10.7326/M15-0970.*

[305] Nelson, H.D., Tyne, K., Naik, A., Bougatsos, C., Chan, B.K., & Humphrey, L. (2009). Screening for breast cancer: Systematic evidence review update for the U.S. Preventive Services Task Force. *Ann Intern Med,* 151(10):727–W242.

negative consequences associated with too many or too few diagnostic mammography and DBT studies performed within the population, evidence from the clinical literature suggests appropriate recall rates should fall between five to 12 percent.[306] [307]

To address the health and clinical risks associated with too many or too few breast cancer screening recalls, in the CY 2022 OPPS/ASC proposed rule (86 FR 42242), we proposed to adopt the Breast Cancer Screening Recall Rates measure beginning with the CY 2023 payment determination using a data collection period of July 1, 2020, to June 30, 2021, and then data collection periods from July 1 through June 30 of the following year starting 3 years before the applicable payment calendar year for subsequent years. We intend for this measure to move facilities toward the 5 to 12 percent range of recall rates. Facilities that are above or below the range should consider implementation of internal quality-improvement procedures to ensure they are not missing cases or recalling individuals unnecessarily. This measure would fill the gap in women's health and oncology care that was left in the Hospital OQR Program portfolio following the removal of the Mammography Follow Up Rates measure (OP–9).[308] More specifically, this measure would directly address the reason OP–9 was removed from the Hospital OQR Program by bringing the measure into alignment with current clinical practice and emerging scientific evidence through the addition of screening and diagnostic DBT (83 FR 59096).[309] [310] [311] [312] [313] [314] [315] [316] The Breast Cancer Screening Recall Rates measure would be added to a measure set focused on imaging efficiency. While this measure, as currently specified, would not provide data on outcomes (that is, the number of patients who were recalled and subsequently diagnosed with cancer), it would give facilities information to use in examining their own imaging practices. Results from the measure could be used to identify opportunities for improving the efficiency and quality of care provided and would be added to a measure set focused on imaging efficiency.

(2) Overview of Measure

This claims-based process measure documents breast cancer screening recall rates at the facility level. The Breast Cancer Screening Recall Rates measure would calculate the percentage of Medicare fee-for-service (FFS) beneficiaries for whom a traditional mammography or DBT screening study was performed that was then followed by a diagnostic mammography, DBT, ultrasound of the breast, or magnetic resonance imaging (MRI) of the breast in an outpatient or office setting on the same day or within 45-calendar days of the index image. In assessing this measure based on clinical quality and efficiency, there are potential negative consequences of high and low mammography and DBT recall rates. A middle-range number is the ideal value for this measure. A high cumulative dose of low-energy radiation can be a consequence of too many false-positive mammography and DBT recall studies. Alternatively, inappropriately low recall rates may lead to delayed diagnoses or undetected cases of breast cancer. The inclusion of DBT in evaluating recall care may improve recall rates and positive predictive values compared to metrics that focus solely on mammography.

Although this measure is not based on a specific clinical guidelines, expert clinical consensus and support from publications in the peer-reviewed literature emphasize the importance of appropriate recall rates.[317] [318] The adoption of this measure could potentially fill a gap in breast cancer screening measures for the Hospital OQR Program. This measure would address the Meaningful Measure priority area of ''Making Care Safer.'' The measure addresses this Meaningful Measure area by: (1) Promoting appropriate use of breast cancer screening and diagnostic imaging by encouraging facilities to aim for a performance score within the target recall range; (2) reducing the harms associated with too many recalls, which can lead to unnecessary radiation exposure, anxiety and distress, and increased costs or resource utilization; [319] [320] and (3) addressing the issue of inappropriately low recall rates, which may lead to delayed diagnoses, diagnoses at a later stage, or undetected cases of breast cancer.[321]

The measure was included on the publicly available ''List of Measures Under Consideration for December 21, 2020,'' a list of measures under consideration for use in various

[306] Carney, P.A., Sickles, E.A., Monsees, B.S., Bassett, L.W., Brenner, R.J., Feig, S.A., Smith, R.A., Rosenberg, R.D., Bogart, T.A., Browning, S., Barry, J.W., Kelly, M.M., Tran, K.A., & Miglioretti, D.L. (2010). Identifying minimally acceptable interpretive performance criteria for screening mammography. *Radiology, 255*(2), 354–361. *https://pubmed.ncbi.nlm.nih.gov/20413750/*.

[307] D'Orsi, C.J., Sickles, E.A., Mendelson, E.B., Morris EA, et al. (2013). ACR BI–RADS® atlas, breast imaging reporting and data system. Reston, VA: American College of Radiology.

[308] CMS finalized OP–9 for removal from the Hospital OQR Program in the CY 2019 Outpatient Payment Prospective System and Ambulatory Surgical Center Payment System final rule (CMS–1695–FC) (83 FR 58818).

[309] Aase, H.S., Holen, A.S., Pedersen, K., Houssami, N., Haldorsen, I.S., Sebuodegard, S., & Hofvind, S. (2019). A randomized controlled trial of digital breast tomosynthesis versus digital mammography in population-based screening in Bergen: Interim analysis of performance indicators from the To-Be trial. 29(3), 1175–1186. doi: 10.1007/s00330–018–5690–x.

[310] Aujero, M.P., Gavenonis, S.C., Benjamin, R., Zhang, Z., & Holt, J.S. (2017). Clinical performance of synthesized two-dimensional mammography combined with tomosynthesis in a large screening population. Radiology, 283(1), 70–76. doi: 10.1148/radiol.2017162674.

[311] Bian, T., Lin, Q., Cui, C., Li, L., Qi, C., Fei, J., & Su, X. (2016). Digital breast tomosynthesis: A new diagnostic method for mass-like lesions in dense breasts. Breast J, 22(5), 535–540. doi: 10.1111/tbj.12622.

[312] Caumo, F., Zorzi, M., Brunelli, S., Romanucci, G., Rella, R., Cugola, L., Bricolo, P., Fedato, C., Montemezzi, S., & Houssami, N. (2018). Digital breast tomosynthesis with synthesized two-dimensional images versus full-field digital mammography for population screening: Outcomes from the Verona screening program. Radiology, 287(1), 37–46. *https://doi.org/10.1148/radiol.2017170745*.

[313] Conant, E.F., Beaber, E.F., Sprague, B.L., Herschorn, S.D., Weaver, D.L., Onega, T., . . . Barlow, W.E. (2016). Breast cancer screening using tomosynthesis in combination with digital mammography compared to digital mammography alone: A cohort study within the PROSPR consortium. Breast Cancer Res Treat, 156(1), 109–116. doi: 10.1007/s10549–016–3695–1.

[314] Pattacini, P., Nitrosi, A., & Giorgi Rossi, P. (2018). Digital mammography versus digital mammography plus tomosynthesis for breast cancer screening: The Reggio Emilia tomosynthesis randomized trial. 288(2), 375–385. doi: 10.1148/radiol.2018172119.

[315] Pozz, A., Corte, A.D., Lakis, M.A., & Jeong, H. (2016). Digital breast tomosynthesis in addition to conventional 2D mammography reduces recall rates and is cost effective. Asian Pac J Cancer Prev, 17(7), 3521–3526.

[316] Skaane, P. (2017). Breast cancer screening with digital breast tomosynthesis. Breast Cancer, 24(1), 32–41. doi: 10.1007/s12282–016–0699–y.

[317] Nelson, H.D., Tyne, K., Naik, A., Bougatsos, C., Chan, B.K., & Humphrey, L. (2009). Screening for breast cancer: Systematic evidence review update for the U.S. Preventive Services Task Force. *Ann Intern Med,* 151(10):727–W242.

[318] D'Orsi, C.J., Sickles, E.A., Mendelson, E.B., Morris EA, et al. (2013). ACR BI–RADS® atlas, breast imaging reporting and data system. Reston, VA: American College of Radiology.

[319] Long, H., Brooks, J.M., Harvie, M., Maxwell, A., & French, D.P. (2019). How do women experience a false-positive test result from breast screening? A systematic review and thematic synthesis of qualitative studies. British journal of cancer, 121(4), 351–358. *https://doi.org/10.1038/s41416-019-0524-4*.

[320] Nelson, H.D., Pappas, M., Cantor, A., Griffin, J., Daeges, M., & Humphrey, L. (2016). Harms of breast cancer screening: systematic review to update the 2009 U.S. preventive services task force recommendation. *Annals of internal medicine, 164*(4), 256–267. *https://doi.org/10.7326/M15-0970*.

[321] Nelson, H.D., Tyne, K., Naik, A., Bougatsos, C., Chan, B.K., & Humphrey, L. (2009). Screening for breast cancer: Systematic evidence review update for the U.S. Preventive Services Task Force. *Ann Intern Med,* 151(10):727–W242.

Medicare programs.[322] In January 2021, the Breast Cancer Screening Recall Rates measure was reviewed by both the MAP's rural health workgroup and hospital workgroup, overseen by the Coordinating Committee (MUC20–0005).[323] Both groups and the Coordinating Committee voted to conditionally support the measure, pending NQF endorsement.[324] Concerns cited during the January 2021 MAP review included: (1) The proposed recall range is not based on clinical practice guidelines, but rather expert consensus and synthesis of findings from the scientific literature; (2) use of a range (as opposed to a targeted high or low value) may be difficult for clinicians, patients, and other stakeholders to interpret; (3) the measure does not address social determinants of health, which may impact the rate of recall at some facilities; and (4) the measure does not provide complementary information about patient outcomes (for example, breast cancer detection rate), which could aid in the interpretation and usefulness of the measure's data.[325] Despite these concerns, some members of the rural health workgroup, hospital workgroup, and Coordinating Committee expressed support of the Breast Cancer Screening Recall Rates measure and noted that feedback provided by the MAP did not preclude measure implementation, given its importance to the clinical community and the public.[326] As a part of measure implementation, we noted that we would develop a suite of education and outreach materials to aid stakeholders in the interpretation of measure performance data (86 FR 42243). These materials would explain the measure structure (including use of a range representing ideal performance) to ensure stakeholders understand values within and outside of the target range. Once implemented, the measure would be re-evaluated annually, which would include a consideration of changes to the evidence base and potential integration of social determinants of health (that is, stratification); updates to the measure specifications would be made iteratively, as appropriate, on an annual basis.

Section 1833(t)(17)(C)(i) of the Act directs the Secretary to develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, as we have noted in previous rulemaking (for example, 75 FR 72065 and 76 FR 74494 for the Hospital OQR and ASCQR Programs, respectively), the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

We have reviewed those NQF-endorsed measures that are related to breast imaging and have not identified any that are appropriate for the measurement of mammography or DBT recall rates specifically. As such, we proposed to adopt this measure for use in the Hospital OQR Program because of its importance to women's health and its ability to fill a gap in CMS' Meaningful Measure portfolio even though it has not yet been reviewed by NQF. Submission for NQF endorsement would be considered for this measure in the future.

(3) Measure Calculation

This claims-based process measure documents breast cancer screening recall rates at the facility level. The Breast Cancer Screening Recall Rates measure would calculate the percentage of Medicare FFS beneficiaries for whom a traditional mammography or DBT screening study was performed that was then followed by a diagnostic mammography, DBT, ultrasound of the breast, or MRI of the breast in an outpatient or office setting on the same day or within 45 days of the index image. Specifically, the measure denominator includes Medicare FFS beneficiaries who received a screening mammography or DBT study at a facility paid under the OPPS. The numerator consists of individuals from the denominator who had a diagnostic mammography study, DBT, ultrasound of the breast, or MRI of the breast following a screening mammography or DBT study on the same day or within 45 days of the screening study. The Breast Cancer Screening Recall Rates measure does not have any exclusions. This measure is not risk adjusted. As a process-of-care measure, the decision to image a beneficiary should not be influenced by sociodemographic status factors; rather, risk adjustment for such sociodemographic factors could potentially mask important inequities in care delivery for beneficiaries seen at facilities providing data for this measure. If performance scores for this measure vary across populations, this may be reflective of differences in the quality of care provided to the diverse populations included in the measure's denominator.

Although this measure is not based on a specific clinical guideline, expert clinical consensus and support from the peer-reviewed literature emphasize the importance of appropriate recall rates.[327] We refer readers to the QualityNet website at *https://qualitynet.cms.gov* for the full measure specifications.

(4) Data Sources

The Breast Cancer Screening Recall Rates measure would be calculated using data from final claims that facilities submit for Medicare beneficiaries enrolled in Medicare FFS. As such, facilities would not have to submit any additional data for this measure. The measurement period for the Breast Cancer Screening Recall Rates measure is 12 months. As noted previously, we would use final claims data from July 1, 2020 to June 30, 2021 to calculate the measure for the CY 2023 payment determination and then data collection periods from July 1 through June 30 of the following year starting 3 years before the applicable payment calendar year for subsequent years.

[322] The National Quality Forum. ''List of Measures Under Consideration for December 21, 2020''. (2020) Accessed May 14, 2021. Available at *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212*.

[323] The National Quality Forum. ''List of Measures Under Consideration for December 21, 2020''. (2020) Accessed May 14, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212*.

[324] Measure Applications Partnership. 2020–2021 Measure Applications Partnership. 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Accessed on May 14, 2021 at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020–2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx*.

[325] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[326] Measure Applications Partnership. 2020–2021 Measure Applications Partnership. 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Accessed on May 14, 2021 at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx*.

[327] Nelson, H.D., Tyne, K., Naik, A., Bougatsos, C., Chan, B.K., & Humphrey, L. (2009). Screening for breast cancer: Systematic evidence review update for the U.S. Preventive Services Task Force. *Ann Intern Med,* 151(10):727–W242.

Please note that claims for the initial patient population would be identified from July 1 through May 17 of each year, with numerator cases occurring from July 1 through June 30 annually. The data would be calculated only for facilities paid under the OPPS for mammography and DBT screening in the hospital outpatient setting. Data from the hospital outpatient and carrier files would be used to determine beneficiary inclusion (for example, a mammography follow-up study can occur in any location and be eligible for inclusion in the measure's numerator).

The following is a summary of the comments we received on this proposal and our responses.

Comment: One commenter supported implementation of the Breast Cancer Screening Recall Rates measure into the Hospital OQR Program but encouraged CMS to rename the metric to Breast Cancer Screening Recall Rates.

Response: We thank the commenter for their suggestion. We are refining the name of the measure to the Breast Cancer Screening Recall Rates measure, as this name more accurately describes what this measure assesses.

Comment: Many commenters supported the addition of Breast Cancer Screening Recall Rates measure to the Hospital OQR Program as proposed. A few commenters believe the Breast Cancer Screening Recall Rates measure fills a measurement gap left in the Hospital OQR Program by the removal of Mammography Follow-Up Rates (OP–9) in the CY 2019 OPPS/ASC PPS final rule with comment period (83 FR 59096 through 59097). One commenter acknowledged the low level of burden associated with reporting of claims-based measures.

Response: We thank the commenters for their support.

Comment: A few commenters did not support the addition of Breast Cancer Screening Recall Rates measure to the Hospital OQR Program based on the removal of the Mammography Follow-Up Rates measure (OP–9) in the CY 2019 OPPS/ASC PPS final rule (83 FR 59096 through 59097). The commenters highlight that the measure would not be useful to patients, as it is not based on a clinical practice guideline, systematic review, meta-analysis, or other experimental form of evidence to demonstrate a connection between public reporting of the measure score and its impact on patient outcomes, which is similar to the reason why the OP–9 measure was removed from the Hospital OQR program.

Many commenters provided input on the usability of the Breast Cancer Screening Recall Rates measure's performance scores, suggesting that patients may not be able to fully interpret a facility's performance score presented in comparison to a target range. Commenters also expressed concern about the evidence-base for the measure's 5 percent to 12 percent target range.

Response: We appreciate the commenters' input on the removal of OP–9 from the Hospital OQR Program. We elected to remove OP–9 as it did not align with current clinical practice. The Breast Cancer Screening Recall Rates measure improves upon the OP–9 technical specifications, which had been in use for nearly 10 years, incorporating digital breast tomosynthesis (DBT) as a screening and diagnostic imaging modality to the measure's denominator and numerator, respectively, and refining guidance for interpretation the measure score by presenting a target performance range. OP–9 provided a ceiling for appropriate rates of recall at 14 percent, but did not present a lower bound (due to a lack of evidence at the time of specification). Thus, we believe that the 5 percent to 12 percent range is more interpretable and useful for patients and other consumers than the previously used metric. We will continue to monitor and evaluate the usefulness and usability of the Breast Cancer Screening Recall Rates measure specifications, and specifically the range, during routine measure reevaluation. Additionally, we will ensure education and outreach materials provide meaningful information on data interpretation for our stakeholders.

We acknowledge commenters' concern about the evidence base on which the Breast Cancer Screening Recall Rates measure is based. We convened a technical expert panel (TEP) to gather input from a breadth of stakeholders while specifying this measure; we also collected feedback from additional members of the clinical community through a listening session during which the measure's draft technical specifications were discussed. Based on these qualitative data, we defined the range for appropriate imaging based on the 2013 Breast Imaging Reporting and Data System (BIRADS) Atlas.[328]

Comment: Several commenters provided feedback on the Breast Cancer Screening Recall Rate measure's technical specifications. One commenter questioned why a benchmark value for the measure's range was not provided. Several commenters disagreed with use of the five percent to 12 percent range for appropriate imaging. A few commenters encouraged CMS to consider exclusion of individuals for whom patient or clinical factors necessitate more frequent recall following screening for breast cancer. A few commenters asked why CMS did not include the Breast Cancer Screening Recall Rates measure in a composite of breast cancer measures. A few commenters encouraged CMS to risk adjust the measure to account for potential inequities in care among racial and ethnic minorities. A commenter suggested the incorporation of additional imaging modalities into the measure's technical specifications.

Response: We appreciate the commenters' recommendations on ways to improve the Breast Cancer Screening Recall Rates measure technical specifications. Rather than providing a single benchmark, we used guidance from the American College of Radiology's 2013 BIRADS Manual to define appropriate recall as between five percent and 12 percent of patients for whom follow-up imaging was performed. If, in the future, a single benchmark value is more appropriate for use in public reporting than a range (based on the release of guidance that appears in a clinical practice guideline or other documentation), we will consider revisions to the measure's specifications accordingly.

With respect to the comments that encourage we risk-adjust the measure to account for potential inequities in care around racial and ethnic minorities, we believe risk adjustment for the Breast Cancer Screening Recall Rates measure could have the effect of masking true differences in care provided to patients of different races, ethnicities, and genders. We will continue to monitor and evaluate results for the Breast Cancer Screening Recall Rates measure to ensure high-quality care is provided to all Medicare fee-for-service patients, regardless of their racial, ethnic or gender identities.

We appreciate input on the structure of the Breast Cancer Screening Recall Rates measure and the composition of its data elements. We will continue to monitor the peer-reviewed evidence and feedback from stakeholders to identify future changes to the technical specifications, including the potential need to exclude individuals with certain clinical or patient-focused characteristics. We will also review the additional imaging modalities suggested by commenters to identify if they are appropriate to include in either the

[328] D'Orsi, C.J., Sickles, E.A., Mendelson, E.B., Morris EA, et al. (2013). ACR BI–RADS® atlas, breast imaging reporting and data system. Reston, VA: American College of Radiology.

measure's denominator or numerator or both. We will consider ways to maximize the value of the Breast Cancer Screening Recall Rates measure including incorporation of facility performance scores into a composite evaluating other types of breast-cancer care.

Comment: One commenter encouraged CMS to engage the clinical community and medical societies in the creation of documentation for implementation of the Breast Cancer Screening Recall Rates measure, including files for education and outreach to its members.

Response: We thank the commenter for their support and welcome feedback from the clinical community and medical societies on the creation of education and outreach resources that would be beneficial for measure implementation.

Comment: One commenter encouraged CMS to perform a dry run of facility performance data prior to implementation of the Breast Cancer Screening Recall Rates measure into the Hospital OQR Program. Another commenter asked CMS to make public reporting of the Breast Cancer Screening Recall Rates measure optional. A third commenter asked CMS to delay implementation of the Breast Cancer Screening Recall Rates measure into the Hospital OQR Program until CY 2025.

Response: We appreciate the feedback received on timing for implementation of the Breast Cancer Screening Recall Rates measure. Because this measure builds upon results presented for OP–9 (prior to its retirement from the Hospital OQR Program in CY 2019), we do not believe a dry run is needed prior to implementation As the Breast Cancer Screening Recall Rates measure closely mirrors the OP–9 technical specifications that were in use within the Hospital OQR Program from 2010 to 2018 and as the measure was publicly reported through April 2020, stakeholders are anticipated to have some familiarity with the measure, Thus, we do not believe data for public reporting of the measure need to be delayed to future years. Further, facilities will receive their claims data, to be used in calculation of the Breast Cancer Screening Recall Rates measure, through a claims detail report (CDR) in 2022, which will allow facilities to identify any errors in processed claims and/or plan for future quality-improvement efforts following implementation of the measure into Hospital OQR.

Comment: A few commenters expressed concern about using data in calculation of the Breast Cancer Screening Recall Rates measure that were processed during the COVID–19 pandemic and encouraged CMS to monitor trends in imaging use during this time.

Response: We appreciate commenters' concern about the impact of COVID–19 pandemic, including delays in care resulting from availability of imaging services and changes in the ways patients accessed care since March 2020. In response to the COVID–19 pandemic, we will not use data from January 1, 2020, through June 30, 2020, for performance calculation.[329] We will continue to monitor trends in utilization and impacts of the COVID–19 pandemic as we implement the Breast Cancer Screening Recall Rates measure.

Comment: Many commenters encouraged CMS to seek National Quality Forum (NQF) endorsement prior to implementation of the Breast Cancer Screening Recall Rates measure into the Hospital OQR Program.

Response: We appreciate commenters' input on the need for NQF endorsement of Breast Cancer Screening Recall Rates measure and will consider how best to leverage NQF endorsement review of the measure following its implementation. We believe the Breast Cancer Screening Recall Rates measure addresses a gap area within the Hospital OQR Program for both cancer care and women's health, and think that addition of this measure to the Program before pursuing NQF endorsement will ensure that the quality of services provided is monitored by CMS.

After consideration of the public comments we received, we are finalizing the adoption Breast Cancer Screening Recall Rates measure (newly designated as OP–39) as proposed.

c. Adoption of the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM Beginning With Voluntary Reporting for the CY 2023 Reporting Period and Mandatory for the CY 2024 Reporting Period/CY 2026 Payment Determination and Subsequent Years

(1) Background

An ST-segment elevation myocardial infarction (STEMI) is a form of heart attack in which there is a complete occlusion of one of the heart arteries.[330] Each year over 250,000 Americans experience a STEMI, approximately 50 percent of whom are Medicare beneficiaries.[331] [332] This is represented on the electrocardiogram as an elevation of the ST segment—the interval between ventricular depolarization and repolarization (which represents the duration of an average ventricular contraction).[333] Time is of the essence in STEMI treatment, and the prompt identification of STEMI and restoration of blood flow to the heart (reperfusion therapy) is a key determinant of health outcomes.[334] [335] [336] Primary percutaneous coronary intervention (PCI), which is the use of balloons and stents to restore blood flow, is the preferred reperfusion modality.[337] The 2013 American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) guidelines recommend the initiation of PCI within 120 minutes from first medical contact (FMC).[338] Specifically, if a patient presents to a PCI-capable facility, primary PCI is recommended within 90 minutes of FMC.[339] If a patient presents to a non-PCI-capable facility, the patient should be expeditiously transported to a PCI-capable facility and receive PCI

[329] *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

[330] Anderson JL, Morrow DA. Acute Myocardial Infarction. *New England Journal of Medicine.* 2017;376(21):2053–2064.

[331] Ward et al. Incidence of Emergency Department Visits for ST-Elevation Myocardial Infarction in a Recent 6-Year Period in the United States. Am J Cardiol. 2015 Jan 15; 115(2): 167–170.

[332] Vallabhajosyula S, Kumar V, Sundaragiri PR, et al. Influence of primary payer status on the management and outcomes of ST-segment elevation myocardial infarction in the United States. *PLoS One.* 2020;15(12):e0243810.

[333] Vogel B, Claessen BE, Arnold SV, Chan D, Cohen DJ, Giannitsis E, Gibson CM, Goto S, Katus HA, Kerneis M, Kimura T, Kunadian V, Pinto DS, Shiomi H, Spertus JA, Steg PG, Mehran R. ST-segment elevation myocardial infarction. (2019). Nature Reviews Disease Primers, 5(39). Available at *https://doi.org/10.1038/s41572-019-0090-3.*

[334] Boersma E, Maas AC, Deckers JW, Simoons ML. Early thrombolytic treatment in acute myocardial infarction: reappraisal of the golden hour. *Lancet.* 1996;348(9030):771–775.

[335] Cannon CP, Gibson CM, Lambrew CT, et al. Relationship of symptom-onset-to-balloon time and door-to-balloon time with mortality in patients undergoing angioplasty for acute myocardial infarction. *Jama.* 2000;283(22):2941–2947.

[336] McNamara RL, Wang Y, Herrin J, et al. Effect of door-to-balloon time on mortality in patients with ST-segment elevation myocardial infarction. *J Am Coll Cardiol.* 2006;47(11):2180–2186.

[337] Anderson JL, Morrow DA. Acute Myocardial Infarction. *New England Journal of Medicine.* 2017;376(21):2053–2064.

[338] O'Gara P, Kushner F, Ascheim D, Casey D, Chung M, de Lemos J, Ettinger S, Fang J, Fesmire F, Franklin B, Granger C, Krumholz H, Linderbaum J, Morrow D, Newby L, Ornato J, Ou N, Radford M, Tamis-Holland J, Tommaso C, Tracy C, Woo Y, Zhao D, Anderson J, Jacobs A, Halperin J, Albert N, Brindis R, Creager M, DeMets D, Guyton R, Hochman J, Kovacs R, Kushner F, Ohman E, Stevenson W, Yancy C. (2013). 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation, 127(4): e362–425. Available at *https://www.ncbi.nlm.nih.gov/pubmed/23247304.*

[339] *Ibid.*

within a total of 120 minutes.[340] However, in care settings where it is not possible for a patient to receive PCI or be transferred and receive primary PCI within the 120-minute timeframe, fibrinolytic therapy (medications to dissolve blood clots and restore flow) should be administered rapidly for reperfusion in the absence of contraindications.[341] The guidelines recommend that eligible patients should receive fibrinolytic therapy within 30 minutes of hospital arrival.

(2) Overview of Measure

The STEMI eCQM measures the percentage of ED patients with a diagnosis of STEMI who received timely delivery of guideline-based reperfusion therapies appropriate for the care setting and delivered in the absence of contraindications. The Meaningful Measures Framework aims to address issues that are most vital to delivering quality, value-based care to improve patient outcomes.[342] In alignment with the Meaningful Measures quality priority of promoting effective prevention and treatment of chronic disease, we believe this STEMI eCQM encourages timely, effective and appropriate treatment using clinical data available in certified electronic health record technology (CEHRT) and that this measure has the potential to reduce adverse health outcomes.

The measure was included on the publicly available ''List of Measures Under Consideration for December 21, 2020,'' a list of measures under consideration for use in various Medicare programs.[343] In January 2021, the STEMI eCQM was reviewed by the MAP's rural health workgroup, hospital workgroup, and Coordinating Committee (MUC20–0004) [344] The MAP rural health workgroup conducted discussions regarding the appropriate treatment time for STEMI and how this may be impacted in rural settings due to proximity and transportation issues, especially with getting someone to a PCI-capable facility, and supported the STEMI eCQM (OP–40) [345] for rural providers in the Hospital OQR Program.[346] The MAP voted to conditionally support the measure, pending NQF endorsement. We note that on-site facilities can perform a PCI (if they have the capability to do so), use fibrinolysis, or they can transfer a patient to a facility that provides PCI. These three treatment scenarios are all captured by the measure, including relative treatment times (non-transfer patients receiving PCI at a PCI capable facility within 90 minutes of arrival and patients transferred from a non-PCI-capable to a PCI-capable facility within 45 minutes).

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities (for example, NQF). We note that section 1833(t)(17) of the Act does not require that each measure we adopt for the Hospital OQR Program be endorsed by a national consensus building entity. We have reviewed and identified two related NQF-endorsed chart-abstracted measures—OP–2 (Fibrinolytic Therapy Received within 30 Minutes of ED Arrival) and OP–3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention).

In section XV.B.3.c. of the CY 2022 OPPS/ASC proposed rule (86 FR 42237), we proposed to remove these two related chart abstracted measures—OP–2 (Fibrinolytic Therapy Received within 30 Minutes of ED Arrival) and OP–3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention)—and replace them with this eCQM. The use of the STEMI eCQM measure, in lieu of the OP–2 and OP–3 measures, would eliminate the need for manual chart-abstraction. It would also broaden the group of measured STEMI patients included in the measure to include patients who present to and receive primary PCI at a PCI-capable facility, which is the vast majority of STEMI patients. The OP–2 and OP–3 measures only include patients presenting to non-PCI-capable facilities who either receive fibrinolytics or are transferred to a PCI-capable facility. The STEMI eCQM better supports compliance with the full group of STEMI patients covered in the 2013 ACCF and AHA guidelines for the management of STEMI by measuring timeliness and appropriateness of care for STEMI.[347] We believe that the STEMI eCQM (OP–40) would efficiently and comprehensively measure timeliness of STEMI care by reducing the burden on facilities currently reporting these two chart-abstracted measures, broadening the STEMI population for which performance scores could be publicly reported, and incorporating contraindications to enhance the clinical applicability of the measure. We refer readers to section XV.B.3.c. of the CY 2022 OPPS/ASC proposed rule (86 FR 42237) and section XV.B.3.c. of this final rule with comment period for further discussion on our proposal to remove the OP–2 and OP–3 measures from the Hospital OQR Program.

As such, in the CY 2022 OPPS/ASC proposed rule (86 FR 42244), we proposed to adopt the STEMI eCQM for use in the Hospital OQR Program because of its importance in measuring timely delivery of guideline-based reperfusion therapies appropriate for the care of ED patients with a diagnosis of STEMI and its ability to fill a gap in CMS' Meaningful Measure portfolio. The measure was submitted to NQF in January 2021 and is under review.

(3) Measure Calculation

The STEMI eCQM is a process measure that assesses the percentage of ED patients aged 18 years or older with a diagnosis of STEMI who received appropriate treatment. The denominator includes all ED patients 18 years or older diagnosed with STEMI who do not have contraindications to fibrinolytic, antithrombotic, and anticoagulation therapies.

The numerator includes:

[340] *Ibid.*

[341] *Ibid.*

[342] Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

[343] The National Quality Forum. (2021). List of Measures under Consideration for December 21, 2020. Accessed March 14, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212.*

[344] The National Quality Forum. (2021). Meeting Summary Measure Applications Partnership Rural Health Workgroup Virtual Review Meeting. Accessed on May 17, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94656.*

[345] The National Quality Forum. (2021). Measure Applications Partnership 2020–2021. Considerations for Implementing Measures in Federal Programs: Clinician, Hospital & PAC/LTC. Accessed on May 17, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94893.*

[346] *Ibid.* Considerations for Implementing Measures in Federal Programs: Clinician, Hospital & PAC/LTC. Accessed on May 17, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94893.*

[347] O'Gara P, Kushner F, Ascheim D, Casey D, Chung M, de Lemos J, Ettinger S, Fang J, Fesmire F, Franklin B, Granger C, Krumholz H, Linderbaum J, Morrow D, Newby L, Ornato J, Ou N, Radford M, Tamis-Holland J, Tommaso C, Tracy C, Woo Y, Zhao D, Anderson J, Jacobs A, Halperin J, Albert N, Brindis R, Creager M, DeMets D, Guyton R, Hochman J, Kovacs R, Kushner F, Ohman E, Stevenson W, Yancy C. (2013). 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation, 127(4): e362–425. Available at *https://www.ncbi.nlm.nih.gov/pubmed/23247304.*

• ED-based STEMI patients whose time from ED arrival to fibrinolytic therapy is 30 minutes or fewer; or

• Non-transfer ED-based STEMI patients who received PCI at a PCI-capable hospital within 90 minutes of arrival; or

• ED-based STEMI patients who were transferred to a PCI-capable hospital within 45 minutes of ED arrival at a non-PCI-capable hospital.

For more information on the STEMI eCQM, we refer readers to the full measure specifications available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website, available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-oqr-ecqms*.

(4) Data Sources

This measure is an eCQM that uses data routinely collected through the EHR and is designed to be calculated by the hospitals' CEHRT using patient-level data and submitted to CMS. In 2020, using data from 2018, the STEMI eCQM was tested at two hospital systems (20 EDs in total) with two different EHR platforms for feasibility, validity, and reliability testing, based on the endorsement criteria outlined by NQF.[348] The feasibility testing showed that the measure is feasible and the key features of the eCQM, such as the code sets and measure logic, were readily interpreted by both sites as assessed by the feasibility scorecard and exit interviews conducted at the two sites. The validity testing results showed a wide range of agreement among data elements between the electronic and manual data extracts. Some data elements were collected but not fully interoperable within providers' EHRs. However, as hospitals and EHR vendors meet ONC requirements for interoperability under the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) and map data elements for interoperability via the FHIR-based API required by December 31, 2022 (85 FR 70075), these data elements would be accessible without special effort.

(5) Implementation

In the CY 2022 OPPS/ASC proposed rule (86 FR 42246), we proposed to start with voluntary reporting beginning with the CY 2023 reporting period and then with mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years. We believe that taking an incremental approach to implementing this measure would allow hospitals time to implement workflow changes as necessary to better prepare for submitting data and to increase familiarity with data submission with the introduction of an eCQM into the Hospital OQR Program. We refer readers to section XV.D.6. of the CY 2022 OPPS/ASC proposed rule (86 FR 42259) and section XV.D.6. of this final rule with comment period for additional information related to eCQM data submission and reporting requirements under the Hospital OQR Program.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Many commenters supported the addition of the STEMI eCQM to the Hospital OQR Program as proposed. Two commenters appreciated the phased implementation approach, which would allow facilities the ability to make the necessary adjustments for data submission over time. A commenter specifically cited the transition from voluntary to mandatory reporting of the STEMI eCQM as a preferred strategy for implementation. Another commenter suggested phasing the STEMI eCQM (OP–40) into Hospital OQR concurrent to the OP–2 and OP–3 removal would give facilities sufficient time to adjust workflows in how care is provided and documented within sites' EHRs. An additional commenter pointed out the importance of ensuring the STEMI eCQM is implemented concurrent to the removal of OP–2 and OP–3, ensuring the transition is seamless. Commenters noted the adoption of the STEMI eCQM is consistent with CMS' move to modernization and use of meaningful measures.

Many commenters expressed support for CMS' plan to remove Fibrinolytic Therapy Received within 30 Minutes of Emergency Department (ED) Arrival (OP–2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP–3), replacing them with the STEMI eCQM as proposed. Several commenters asserted that the STEMI eCQM is less burdensome for collection and reporting. They noted the replacement of OP–2 and OP–3 with the STEMI eCQM would reduce burden on facilities to abstract information about a sample of cases for each measure quarterly and would provide more precise, evidence-based guidance for how to interpret the STEMI eCQM's quality actions in the numerator.

Response: We thank the commenters for their support.

Comment: One commenter encouraged CMS to delay removal of OP–2 and OP–3 from the Hospital OQR Program until the STEMI eCQM is implemented and data are available for public reporting. Another commenter recommended CMS retain OP–2 and OP–3 in the Hospital OQR Program as optional measures for facilities with limited resources for eCQM reporting.

Response: We appreciate commenters' position on retention of OP–2 and OP–3 as optional measures or for additional years. However, we believe the incremental approach we proposed for implementation of the STEMI eCQM will give facilities sufficient time to meet requirements under the ONC's requirements for interoperability through the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) and to map data elements for interoperability via the FHIR based API (85 FR 70075). Additionally, to delay removal of OP–2 and OP–3 or to retain them as optional measures would undermine the incremental nature of our implementation. Retaining these measures may cause hospitals to delay their implementation of the STEMI eCQM until the last minute. Thus, we believe that the delayed implementation or retention of OP–2 and OP–3 is not necessary.

Comment: Several commenters encouraged CMS to delay implementation of the STEMI eCQM until the measure obtains endorsement by the NQF.

Response: We appreciate commenters' concern about delaying implementation of this measure into the Hospital OQR program until they are endorsed by NQF. We submitted the STEMI eCQM for endorsement review through NQF's Cardiovascular Project in spring 2021. The NQF Cardiovascular Standing Committee passed the measure on all criteria and on overall suitability for endorsement.[349] At the close of comment period for the CY 2022 OPPS/ASC PPS proposed rule, the STEMI eCQM was undergoing public comment through NQF and would receive review by NQF's Consensus Standards Advisory Committee (CSAC) in fall 2021. Should it be approved by the CSAC, the STEMI eCQM will be endorsed by NQF as #3613e.

As noted in section XV.D.4.a.(2)(c). of this final rule with comment period, CMS is not limited by section 1833(t)(17) of the Act to select measures for the Hospital OQR Program that have been approved by a consensus base

[348] National Quality Forum. What NQF Endorsement Means. Available at: *https://www.qualityforum.org/Measuring_Performance/ABCs/What_NQF_Endorsement_Means.aspx*.

[349] National Quality Forum. (2021). Cardiovascular Spring 2021 Cycle: CDP Report: Draft Report for Comment. Accessed on September 21, 2021, at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96018*.

entity such as NQF. Given the broad support for the measure obtained during development, including support from the TEP, during measure development public comment, and by the MAP's Rural Health Advisory group, Hospital Workgroup, Coordinating Committee, and MAP public comment, as well as the benefits of the STEMI eCQM over the OP–2 and OP–3 measures, we believe it is critical to implement this measure on the timeline discussed above even if the measure does not obtain NQF endorsement in fall 2021.

Comment: Several commenters recommended CMS support facilities, vendors, and other stakeholders during the implementation of the STEMI eCQM into the Hospital OQR program, as it would be the first eCQM added to the program. Specifically, a few commenters expressed concern about the costs associated with initial implementation of eCQMs (for example, building eCQM logic, validation, certification, etc.) and the timing by which EHR standards must be in place to meet the deadline for voluntary reporting.

Response: We appreciate commenters' concern regarding the start-up costs and requirements for eCQM reporting. However, data elements for the STEMI eCQM are all readily available in structured fields (or will be, based on the FHIR-based API, which is required for implementation by December 31, 2022 (85 FR 70075)). The proposed measure also aligns with interoperability guidance from the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) published May 1, 2020, therefore facilities and vendors have received advanced notice and guidance on FHIR API standardization that will support the transition to eCQMs. We also note that many facilities have operationalized and gained experience in reporting eCQM for the Hospital IQR Program. Thus, we believe that many facilities have demonstrated readiness in reporting eCQM and the implementation burden will not exceed requirements from other federal regulation already in place.

Additionally, we will provide assistance to facilities, vendors, and other stakeholders through the release of education and outreach materials following adoption of the measure in the program.

Comment: One commenter expressed concern about external factors (such as delays in resuscitation or a family's decision to not pursue aggressive care) that could affect facility performance through no fault of the clinician. This commenter encouraged CMS to exclude these cases to avoid penalization of the facility for care that does not meet the numerator's quality action.

Response: We appreciate the commenter's feedback on measure exclusions and considered these issues during measure development. Certain delays in resuscitation, such as cardiopulmonary arrest, are contraindicated and therefore excluded from the measure. We found that family refusal is not consistently captured in a structured data field. For this reason, we believe that family refusal cannot be reliably used an exclusion criterion at this time.

Comment: One commenter questioned how patients for whom a contraindication to fibrinolytic therapy would be excluded from the STEMI eCQM's initial patient population.

Response: We thank the commenter for their question. To clarify, we specified the measure's exclusions to remove a patient if the patient presents with any of a breadth of clinical diagnoses that reflect a contraindication to fibrinolytic therapy (such as suspected aortic dissection, ischemic stroke, intracranial or intraspinal surgery, etc.); a full list of exclusions for the STEMI eCQM is available on HealthIT.gov (*https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/1/cms996v2*).

We will monitor and evaluate additional clinical reasons for not using fibrinolytics to treat a myocardial infarction as this information becomes available.

Comment: One commenter asked how CMS would use data from third-party electrocardiograms (ECGs) in identifying patients for inclusion in the measure's initial population.

Response: We thank the commenter for their feedback. At this time, data from ECGs are not used to identify the STEMI eCQM's initial patient population. Rather, individuals are identified for inclusion in the measure if they were diagnosed with a myocardial infarction and did not have documentation of one or more excluded condition. The full technical specifications for the measure are available on *HealthIT.gov*.[350]

Comment: A commenter encouraged CMS to perform larger-scale testing and a feasibility assessment for implementation, expanding upon the two sites at which electronic health record (EHR) testing occurred previously, to ensure the measure is truly reliable and valid.

Response: We appreciate the commenter's concern about measure testing. With regards to measure reliability and validity, the NQF Cardiovascular Project's Standing Committee performed an evaluation of the measure's reliability and validity. They concluded that the results represented a moderate level of scientific acceptability. The measure was tested using data from two large hospital systems (with 20 EDs), whereby one system treated a large number, and the second system treated a smaller number of STEMI patients during the data period used for testing. As noted in section XV.B.4.c.(4) of this final rule with comment period, the feasibility testing showed that the measure is feasible and the key features of the eCQM, such as the code sets and measure logic, were readily interpreted by both sites as assessed by the feasibility scorecard and exit interviews conducted at two systems. The validity testing results showed a wide range of agreement among data elements between the electronic and manual data extracts. Statistical methods indicate equivalent agreement that the denominator value is expected by chance in the first system and slight agreement in the second system, with a moderate indication of denominator exclusion values in both EHR systems.[351] With regards to the test sites and EHR systems tested, the two EHR vendors utilized by the two hospital systems tested constitute the vast majority of EHRs.

After consideration of the public comments we received, we are finalizing the adoption of STEMI eCQM (Newly designated as OP–40) as proposed.

5. Modifications to Previously Adopted Measures

a. Requiring OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With Voluntary Reporting for the CY 2023 Reporting Period and Mandatory Reporting Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination and for Subsequent Years

We previously adopted the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) measures to assess patient experience with care following a procedure or surgery in a HOPD. These survey-based

[350] (*https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/1/cms996v2*).

[351] National Quality Forum. (2021). Cardiovascular Spring 2021 Cycle: CDP Report: Draft Report for Comment. Accessed on September 21, 2021, at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96018*.

measures rate patient experience as a means for empowering patients and improving the quality of their care (82 FR 59432). For further details on these measures, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79771 through 79784), in which we adopted these measures beginning with the CY 2020 payment determination.

Subsequently, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433), we delayed implementation of OP–37a–e for the Hospital OQR Program beginning with the CY 2020 payment determination due to lack of sufficient operational and implementation data. At that time, we believed that our ongoing National OAS CAHPS voluntary reporting program for the survey measures, which began in January 2016 [352] and is unrelated to either the Hospital OQR Program or ASCQR Program, would provide valuable information moving forward. Specifically, we wanted to use the information from the National OAS CAHPS voluntary reporting program to: (1) Ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; (2) reaffirm the reliability of national implementation of OAS CAHPS Survey data; and (3) appropriately account for the burden associated with administering the survey in the outpatient setting of care.

In the CY 2022 OPPS/ASC proposed rule (86 FR 42246), we proposed to restart the OP–37a–e measure by requiring the measure in the Hospital OQR Program beginning with the CY 2024 reporting period/CY 2026 payment determination. Specifically, for the Hospital OQR Program, we proposed voluntary data collection and reporting beginning with the CY 2023 reporting period, followed by mandatory data collection and reporting beginning with the CY 2024 reporting period/CY 2026 payment determination. As noted previously, the National OAS CAHPS voluntary reporting program is independent of the Hospital OQR Program and the ASCQR Program. As proposed in the CY 2022 OPPS/ASC proposed rule (86 FR 42246), our intent is to make the distinction that HOPDs that voluntarily report the OAS CAHPS Survey-based measures during the CY 2023 reporting period would do so as part of the Hospital OQR Program until mandatory reporting begins. The reporting process for HOPDs to submit OAS CAHPS Survey data would remain unchanged. That is, HOPDs would submit OAS CAHPS Survey data through their vendors, who would submit these data to CMS as appropriate. We refer readers to section XV.D.4.b. of the preamble of the CY 2022 OPPS/ASC proposed rule (86 FR 42258) and of this final rule with comment period for our related proposals regarding the form, manner, and timing for reporting the OP–37a–e Survey-based measures.

Having had the opportunity during the delayed implementation to investigate the concerns about patient response rates and data reliability, we believe that patients are able to respond to OAS CAHPS Survey questions, and that those responses are reliable based on our prior experiences collecting voluntary data for public reporting since CY 2016 (available at *https://data.cms.gov/provider-data/*). We reaffirm that the OAS CAHPS Survey-based measures assess important aspects of care where the patient is the best or only source of information (81 FR 79771). Furthermore, in section XV.D.4.b.(1). of the CY 2022 OPPS/ASC proposed rule (86 FR 42258), we proposed additional collection modes using a web-based module (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents) for administering the survey, which would be available beginning in CY 2023 under the Hospital OQR Program and for subsequent years.[353] We believe this would address some burden concerns raised during the CY 2017 OPPS/ASC final rule with comment period (81 FR 79777) because the web-based modules would produce similar results but at lower costs of collection.[354] We also continue to believe that the benefits of this measure, such as giving patients the opportunity to compare and assess quality of care in the outpatient setting in a standardized and comparable manner, outweigh the burdens (81 FR 79778). As we stated in the CY 2018 OPPS/ASC final rule with comment period, we continue to believe that implementation of these measures will enable objective and meaningful comparisons between hospital outpatient departments (82 FR 59432) and rating patient experience still provides important information to hospital outpatient departments and patients and enables objective and meaningful comparisons between hospital outpatient departments (82 FR 59432).

We refer readers to section XV.D.4.b. of the CY 2022 OPPS/ASC proposed rule (86 FR 42258) and of this final rule with comment period for our related proposals regarding form, manner, and timing for reporting the OP–37a–e Survey-based measures.

We received comments on these topics.

Comment: A few commenters supported the voluntary collection of OAS CAHPS Survey in the Hospital OQR Program beginning in CY 2023 reporting period.

Response: We thank the commenters for their support.

Comment: A few commenters supported voluntary collection of the OAS CAHPS Survey and recommended releasing additional information regarding operational or technical knowledge learned during the voluntary period prior to the start of mandatory reporting.

Response: We agree that information learned during the OAS CAHPS Survey voluntary reporting period and the National OAS CAHPS Survey voluntary reporting program should be disseminated to HOPDs to help improve their performance and patient safety. For information about the National OAS CAHPS Survey voluntary reporting, we encourage hospitals to visit: *https://oascahps.org/General-Information/National-Implementation*. We believe the information learned through this prior voluntary reporting timeframe can inform practice during the voluntary reporting period and eventually mandatory reporting as part of the Hospital OQR Program. Specifically, as part of the National OAS CAHPS Survey voluntary reporting, a summary report that includes information about patient-mix adjustments for each quarter is updated and posted before each quarterly data submission period. Preview reports for each facility participating voluntarily is posted on the OAS CAHPS website two weeks prior to public reporting. The Protocols and Guidelines Manual is updated annually with any necessary clarifications about participation requirements and protocols. Training has been provided annually to approved

[352] Participation in the program is open to any interested Medicare-certified Hospital Outpatient Departments (HOPDs) and free-standing ambulatory surgery centers (ASCs). More information on the National OAS CAHPS voluntary reporting program is available at: *https://oascahps.org/General-Information/National-Implementation* and *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS/OAS-CAHPS*.

[353] We note that the mixed modes will be available as part of the National OAS CAHPS voluntary reporting program beginning in CY 2022.

[354] Bergeson SC, Gray J, Ehrmantraut LA, Laibson T, Hays RD. Comparing Web-based with Mail Survey Administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Clinician and Group Survey. Prim Health Care. 2013;3:1000132. doi:10.4172/2167–1079.1000132.

vendors to clarify administration protocols. We refer reader to *https://oascahps.org/Training/Training-Materials* for more information.

Comment: Several commenters supported the mandatory collection of the OAS CAHPS Survey in the Hospital OQR Program. One commenter stated that the OAS CAHPS Survey will help HOPDs strategically identify strengths, weaknesses, and areas for improvement related for patient experience.

Response: We appreciate the support of mandatory reporting of OAS CAHPS Survey as part of the Hospital OQR program. We believe that these survey-based measures will be useful to assess aspects of care where the patient is the best or only source of information, and to enable objective and meaningful comparisons between HOPDs. We also believe this feedback will help HOPDs identify and improve patient related experiences.

Comment: A few commenters expressed concern with the OAS CAHPS Survey use of CPT codes. These commenters also expressed concern that these codes were not consistent with certain IT vendor support. Another recommended that OAS CAHPS Survey patient eligibility should not rely on CPT codes. A commenter expressed concern surrounding the timeframe around submission of claims and coding information simply does not match—meaning that coding may not be completed to accommodate the 21- to 60-day survey timeframe and recommended that CMS to eliminate the use of CPT codes to trigger survey distribution.

Response: We appreciate this feedback. We interpret the commenters' concern to be that there may be confusion over which patients would be eligible to be surveyed as part of the OAS CAHPS Survey reporting. We note that the OAS CAHPS Survey is administered to all eligible patients, or a random sample thereof, who had at least one outpatient surgery/procedure during the applicable month. Many CPT codes have been excluded from inclusion in the OAS CAHPS Survey, including services like application of a cast or splint, in order to ensure that only patients receiving applicable procedures are surveyed.[355]

With regard to the timing of the availability of CPT codes for sample selection, we recognize in some cases there could be delays in getting the CPT codes updated in the patient record and transmitted to the survey vendor in a timely manner. Under the current protocol for survey administration, we allow survey vendors to work with HOPD and ASC facilities to identify alternative ways to identify the patient records for outpatient surgery or diagnostic procedures that were performed in eligible HOPDs or ASCs (as identified by the facility-level eligibility criteria). Vendors can submit exception requests to request alternative methods for identifying the eligible population. We also note that the current protocol for survey administration allows for late start requests for situations in which the complete patient records are not available within the target window of time for survey administration. Vendors can submit late start requests when the patient data file is received more than 26 days after the sample month. This allows for flexibility in situations when the CPT codes are not available initially but can be updated. Further, sampling is allowed to proceed if 90 percent of the patient records have CPT codes. Updates to the Survey Specifications and Guidelines will be available on the OAS CAHPS Survey website.[356] We will take all comments under consideration as we consider future refinements for the OAS CAHPS Survey.

Comment: A few commenters expressed concern that there is little variation in performance scores for this measure.

Response: We thank the commenters for their feedback. Performance scores are measured and reported publicly at the facility, state, and national levels through the Provider Data Catalog (PDC) datasets (*https://data.cms.gov/provider-data/*). OAS CAHPS Survey results are publicly reported as ''top-box'', ''bottom-box'', ''middle-box'', and ''linear scaled scores''. The scores are adjusted for patient mix within each quarter to account for facility differences in patient mix. During voluntary participation, facilities may choose to have their survey results published or only reported privately through preview reports. Variation in performance scores is expected to increase as more facilities participate. We believe that the OAS CAHPS Survey-based measures will be useful to assess aspects of care where the patient is the best or only source of information, and to enable objective and meaningful comparisons between HOPDs.

Comment: A commenter opposed mandatory reporting for OAS CAHPS Survey, expressing concern regarding its reliability. This commenter also expressed the belief that many of the issues from when the measure was originally delayed have not yet been resolved, namely the potential for low patient response rate, administration burden on providers and lack of reliable national OAS CAHPS Survey data.

Response: We thank the commenter for their feedback and acknowledge their concern. We believe that OAS CAHPS Survey is reliable and that our prior concerns that resulted in the delay of the OAS CAHPS Survey implementation have been resolved. HOPDs have been able to report OAS CAHPS Survey data as part of the National OAS CAHPS Survey since 2016. Based on our experience through this reporting, we are able to: (1) Ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; (2) reaffirm the reliability of national implementation of OAS CAHPS Survey data; and (3) appropriately account for the burden associated with administering the survey in the outpatient setting of care. We also note that, unit-level reliability analysis of the publicly reported composites for OAS CAHPS are well above the .70 cut-off typically used to assess reliability of a measure.

Comment: A few commenters opposed mandatory reporting and expressed concern regarding the financial burden of OAS CAHPS Survey vendors, and IT resource strain. Several commenters opposed mandatory reporting due to the operational burden on patients and facilities, as well as the repetitive nature of this extensive and complex outpatient survey.

Response: We thank these commenters for their feedback and acknowledge their concerns. While there are administrative and financial burdens associated with implementing the OAS CAHPS Survey and OAS CAHPS Survey-based measures in the Hospital OQR Program, we believe the benefits of capturing patient experience of care data in the HOPD setting outweigh the burdens. In selecting measures for the Hospital OQR Program, we weigh the relevance and utility of measures against the potential burden to HOPDs resulting from the measure's adoption, and we believe the OAS CAHPS Survey is a vital source of information in assessing the quality of care provided at an HOPD.

We post the list of the approved OAS CAHPS Survey vendors on *https://oascahps.org* and we encourage HOPDs to contact vendors for cost and service information pertaining to OAS CAHPS Survey as there may be differences among vendors and multiple modes of

[355] Updates on OAS CAHPS Survey specifications and guidelines are available at *https://oascahps.org/General-Information/Announcements.*

[356] *https://oascahps.org/.*

conducting the survey provide greater economical choice.

In addition, we address additional modes to collect OAS CAHPS Survey data in section XVI.D.4.b.(1) of the CY 2022 ASC/OPPS proposed rule (86 FR 42258) which we expect to reduce the future cost of administration. We refer readers to the Protocols and Guidelines Manual for the OAS CAHPS Survey (*https://oascahps.org/Survey-Materials*) for materials for each mode of survey administration.

With respect to the burden on patients, we believe that patients appreciate the opportunity to provide feedback to their providers and that the information learned from their responses has the potential to improve communication and care that HOPDs provide and can simply opt not to respond to the survey if so inclined.

Further, while we did not propose a solely digital mode of conducting the OAS CAHPS Survey, we will continue to analyze whether a web-only or digital-only format would be appropriate for the OAS CAHPS Survey, which could potentially further reduce the costs of administering the survey.

Comment: A few commenters opposed mandatory reporting and cited staffing shortages and the ongoing COVID–19 crisis as reasons for opposing the mandatory adoption of OAS CAHPS Survey at this time.

Response: We understand the commenters' concerns and the aim to accommodate HOPDs while our nation works through the unprecedented COVID–19 pandemic. However, we believe the OAS CAHPS Survey is a critical measure of patient experience at this time. We also note that, since many hospitals already have vendors in place and are successfully reporting the HCAHPS Survey in the IQR program, the burden of finding a vendor and operationalizing the OAS CAHPS is minimal.

Comment: A commenter expressed concern that there is overlap between CAHPS Surveys that would be administered by Clinician Groups, Outpatient/ASCs, as well as from Surgical Care teams and that there is potential for patients to receive multiple requests to complete CAHPS Surveys in connection with a single episode of care, causing confusion and survey fatigue.

Response: While we understand the commenter's concerns regarding resources needed to collect the survey, and survey administration burden for hospitals, the OAS CAHPS Survey was developed for use in assessing patient experience of care for select outpatient surgical procedures. We are dedicated to improving the quality of care provided to patients, and believe patients are a vital source of information in assessing the quality of care provided at a hospital outpatient department. We believe that the benefits of this measure, such as giving patients the opportunity to compare and assess quality of care in the outpatient setting in a standardized and comparable manner, outweigh the burdens.

Regarding confusion among patients and multiple overlapping survey tools, we note that other CAHPS Surveys, such as the HCAHPS Survey, are tailored to different aspects of care provided by hospitals, such as inpatient care. In addition, the survey introduction (and letter) provided to patients includes the date and location of the surgery or procedure that the patient received at the facility. Furthermore, patients will also be reminded of the date and location of the surgery or procedure they received during the telephone interviews. For these reasons, we do not believe there will be issues associated with overlap or confusion for these surveys.

Comment: A commenter expressed concern that departments may have multiple sets of patient experience results and recommended applying the OAS CAHPS Survey for only people who have a day surgery where anesthesia is used.

Response: We thank the commenter for their suggestion; however, we believe that the OAS CAHPS Survey is appropriately scoped to provide patients and facilities meaningful data on the services provided by HOPDs and not just those that require anesthesia.

Comment: A few commenters opposed the OAS CAHPS Survey measures because the OAS CAHPS is not endorsed by the NQF. The commenters encouraged CMS to pursue NQF endorsement of these measures before the OAS CAHPS Survey is required in order to ensure all stakeholders are given insight into the measure and to ensure it is fair and accurate.

Response: We thank commenters for their feedback. We note, section 1833(t)(17) of the Act does not require that each measure we select for the Hospital OQR Program be endorsed by a national consensus building entity, or the NQF specifically. Under this paragraph, the Secretary has the authority to select non-endorsed measures. While we strive to develop NQF-endorsed measures, including when feasible and practicable, we believe the requirement that measures developed by the Secretary for use in the Hospital OQR Program reflect consensus among affected parties can be achieved in other ways, including through the measure development process, which often includes stakeholder input via a Technical Expert Panel (TEP), review by the MAP, broad acceptance and use of the measure, and public comments.

We also believe that lack of NQF endorsement does not limit insight into whether the measures portray hospital performance in a fair and accurate manner. The survey was tested in both the outpatient and ASC settings in 2014 (field testing) and 2015 and 2019 (mode testing) was found to be reliable. We refer readers to *https://oascahps.org/* for more information about field and mode testing for these measures. The OAS CAHPS Survey development process followed the principles and guidelines outlined by AHRQ and its CAHPS Consortium.[357] This process included: (1) Reviewing existing literature; (2) reviewing surveys submitted under a public call for measures; (3) conducting focus groups with patients who had recent outpatient surgery; (4) conducting cognitive interviews with patients to assess their understanding and ability to answer survey questions; (5) obtaining stakeholder input on the draft survey and other issues that may affect implementation; conducting a field test; and (6) conducting a test of the various data collection mode effects on survey responses.

Comment: One commenter strongly recommended that CMS reconsider its position on respondent confidentiality and remove the requirement to include the question on consent to share identifying information from the OAS CAHPS Survey if the facility is interested in receiving patient-level response data connected to the patient's identifying data. Another commenter explained that if facilities understood the patient, they could more easily provide their employees immediate, and targeted improvement training. One commenter recommended that CMS align the OAS CAHPS patient confidentiality rules with HCAHPS, which allows for the release of patient-level data for quality improvement purposes with the stipulation that the patient identity should not be shared with direct care staff. Another commenter expressed concern about a question on the OAS CAHPS Survey that seeks information on ''Consent to Share Identifying Information'', believing that the question limits the

[357] Agency for Healthcare Research and Quality. ''The CAHPS Program.'' Available at: *https://ahrq.gov/cahps/index.html.*

ability to identify trends and thereby limits opportunities.

Response: We thank these commenters for their feedback. While the desire to have patient identifying information to develop responsive training and remediation steps is admirable, we believe that patient confidentiality is an important aspect of the OAS CAHPS Survey to help encourage accurate reporting. The administration protocols for the OAS CAHPS Survey follow protocols for CAHPS® Surveys, restricting the release of patient-level data if the patient has not consented. We note that for the Hospital IQR Program, we do not state that patients' responses and identifying information will not be shared with the hospital because hospitals can self-administer the HCAHPS Survey. However, for surveys administered via a third-party vendor, the survey is not linked to a sample patient's name unless the patient gives his or her consent. We note that facilities may choose to add the ''Consent to Share'' question to the OAS CAHPS Survey, which asks whether a patient gives permission for their name to be linked to their survey responses. However, we note that each facility should consult with its own counsel to ensure compliance with applicable privacy and security laws.

Comment: A requester sought clarification on whether the OAS CAHPS Survey will be mandated in CY 2024 if outpatient surgery is included in their HCAHPS submission.

Response: The Hospital OQR Program is an independent quality reporting program, and as part of its requirements, HOPDs will be required to meet the reporting requirement for the OAS CAHPS Survey once the OAS CAHPS Survey begins mandatory reporting in CY 2024 reporting period/CY 2026 payment determination.

Comment: A commenter requested that CMS do more to ensure correct attribution of experience and requested CMS provide evidence of the survey's reliability before it requires survey administration, which the commenter believes could reduce the reliability of the results and negatively impact data-driven decision making.

Response: We thank the commenter for their feedback. The purpose of the OAS CAHPS Survey is to obtain data on a patient's experience of care received from a hospital/facility, specifically from an HOPD. While there is always potential that a patient gets confused, we believe that the OAS CAHPS Survey is focused on patients' experience of care received for their ambulatory surgery or procedure. A physician/surgeon who performs surgeries/procedures at a facility is a member of that facility with both rights and responsibilities. We believe it is the facility's responsibility to ensure that someone—whether the doctor, nurse, or other facility staff member—provide patients with information about preparing for their procedure, about the procedure itself, as well as what to expect following the procedure/surgery. Therefore, we believe it is appropriate to include these important communications with patients in the OAS CAHPS Survey and believe experience with the provider attributed to the facility is appropriate.

Further, we believe that the information provided in the OAS CAHPS Survey ''Instructions'' is sufficient to inform the patient regarding the purpose of the OAS CAHPS Survey and provides sufficient instruction and details for the patient to correctly identify and relate the survey to the facility and procedure that patient received. We began developing the Outpatient and Ambulatory Surgery Survey in 2012 using the principles and guidelines established by the Agency for Healthcare Research and Quality's (AHRQ) CAHPS program and AHRQ approved this instrument as a CAHPS Survey in February 2015.[358]

We reiterate that based on our experience through the National OAS CAHPS voluntary reporting program, we can confirm the OAS CAHPS Survey reliability and (1) ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; (2) reaffirm the reliability of national implementation of OAS CAHPS Survey data; and (3) appropriately account for the burden associated with administering the survey in the outpatient setting of care. We also note that, unit-level reliability analysis of the publicly reported composites for OAS CAHPS are well above the .70 cut-off typically used to assess reliability of a measure. Based on this reliability, we believe that the information learned from the survey data will allow hospitals to make more informed decisions to improve care.

Comment: Many commenters expressed concern regarding the length of the survey and recommended that the survey should be significantly shortened to focus on actionable aspects of the patient experience and to encourage higher response rates amongst patients. Specifically, some commenters recommended that a revised OAS CAHPS Survey should include five to ten questions.

Response: The OAS CAHPS Survey is comparable in length and survey response rate to other patient experience of care surveys. The survey instrument was developed in order to provide a more complete picture of patients' experience of care in the HOPD setting. We believe allowing facilities to administer a selection of the survey items, or greatly reducing the questions to patients would impair the assessment of a facility's quality of care and would also inhibit the comparison of performance across facilities and the reliability of a facility's scores. In addition, the 24 core questions of the OAS CAHPS Survey are either directly actionable (that is, give feedback to hospitals) or inform the need for patients to answer subsequent questions that are actionable. We note that the survey results to date do not show that respondents are terminating the interview before the last question, which would be an indication of respondent fatigue for a survey that is too long. Based on the most recently received national implementation data for voluntary reporting, the nonresponse due to terminated interviews is less than one percent.

Implementing the OAS CAHPS Survey in the Hospital OQR Program will enable patients to compare patient experience of care data across multiple HOPDs as part of their healthcare decision-making. In addition, we believe implementing the OAS CAHPS Survey in the Hospital OQR Program will incentivize HOPDs to factor patient experience of care into their quality improvement efforts more proactively. Implementing a shorter ''sample survey'' would not enable the same type of comparison as a fully tested survey.

However, we also acknowledge these commenters' concerns about the length of the OAS CAHPS Survey and will continue to consider whether refinement would be appropriate.

Comment: A commenter sought more information regarding the future of the ''Preparations for Discharge and Recovery'' domain of the OAS CAHPS Survey and whether CMS will publicly report data collected from the domain.

Response: We plan to report information from ''Preparations for Discharge and Recovery'' beginning with the data collected in 2022 as part of National OAS CAHPS voluntary reporting and address public reporting OAS CAHPS data as part of the Hospital OQR Program in future rulemaking.

After consideration of the public comments we received, we are finalizing this proposal as proposed.

[358] *See https://www.ahrq.gov/cahps/surveys-guidance/oas/index.html.*

We also refer readers to section XVI.B.4.c. of this final rule with comment period where we are also finalizing this measure in the ASCQR program with modification.

b. OP–31: Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536) Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75102 through 75104) we finalized the adoption of the OP–31: Cataracts: Improvement in Patient's Visual Function with 90 Days Following Cataract Surgery [359] measure beginning with the CY 2016 payment determination. This measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery (78 FR 75102) via the administration of pre-operative and post-operative visual function surveys.

During the CY 2014 OPPS/ASC proposed rule, some commenters expressed concern about the burden of collecting pre-operative and post-operative visual function surveys (78 FR 75103). In response to those comments, we modified and finalized our implementation strategy in a manner that we believed would significantly minimize collection and reporting burden (78 FR 75103). Specifically, we applied a sampling scheme and a low case threshold exemption to address commenters' concerns regarding burden (78 FR 75114). With those changes, we intended to decrease burden and facilitate data reporting by allowing random sampling of cases when volume is high, instead of collecting information for all eligible patients (78 FR 75114). For further details, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75102 through 75104).

Shortly thereafter, we became concerned about the use of inconsistent surveys to assess visual function. The measure specifications allowed for the use of any validated survey and we were not positive about the impact the use of varying surveys might have. Therefore, we issued guidance stating that we would delay the implementation of OP–31.[360] Subsequently, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66947 through 66948), we finalized our proposal to exclude OP–31 from the CY 2016 payment determination measure set, and for subsequent years. In addition, we finalized allowing hospitals to voluntarily report OP–31 data for the CY 2015 reporting period/CY 2017 payment determination and subsequent years (79 FR 66948).

(2) OP–31 Measure Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination and for Subsequent Years

In the CY 2022 OPPS/ASC proposed rule (86 FR 42247), we stated that we believed it would be appropriate to require hospitals to report on OP–31. We stated that hospitals have had the opportunity for several years to familiarize themselves with OP–31, prepare to operationalize it, and opportunity to practice reporting the measure since the CY 2015 reporting period/CY 2017 payment determination. We noted that a small number of facilities have consistently reported data for this measure and these data have been made publicly available. While we previously had concerns regarding the use of different surveys to assess visual function (79 FR 66947), we believe that using different surveys will not result in inconsistencies, as the allowable surveys are scientifically validated and provide comparable results.[361] Research has demonstrated that of 16 different cataract surgery outcome questionnaires, it has been demonstrated that all were able to detect clinically important change.[362]

In the CY 2022 OPPS/ASC proposed rule (86 FR 42247), we proposed to require reporting of the OP–31 measure beginning with the CY 2023 reporting period/CY 2025 payment determination and for subsequent years. As we stated in the CY 2014 OPPS/ASC final rule with comment period, as well as the CY 2015 OPPS/ASC final rule with comment period, and consistent with the MAP recommendation, we continue to maintain that this measure ''addresses a high-impact condition'' that is not otherwise adequately addressed in our current measure set (78 FR 75103 and 79 FR 66947, respectively). Moreover, OP–31 serves to improve patient-centered care by representing an important patient reported outcome (78 FR 75103). This measure provides opportunities for care coordination as well as direct patient feedback.

We refer readers to section XV.D.5.a. of the CY 2022 OPPS/ASC proposed rule (86 FR 42259) and section XV.D.5.a.(1). of this final rule with comment period for information about submitting data via a CMS web-based tool.

We received comments on these topics.

Comment: Several commenters expressed support for mandatory reporting of OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

Response: We thank the commenters for their support. The implementation of this measure underwent a number of changes aimed to address previous concerns regarding burden and the usage of various surveys to assess visual function. However, after review of public comments, which are discussed in this section, we are finalizing to require the OP–31 measure beginning with the CY 2025 reporting period/CY 2027 payment determination, instead of our originally proposed data collection beginning with the CY 2023 reporting period.

Comment: A few commenters expressed concern about making this measure mandatory, stating that because the OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure is not currently mandatory, many facilities have not been ''practicing'' reporting it even though it is voluntary in the Hospital OQR Program measure set.

Response: We thank the commenters for their feedback. We note that even though a small number of facilities have reported data for this measure, those that have reported on this measure have done so successfully and consistently. We believe the 2-year extension from our originally proposed timeline of the CY 2023 reporting period/CY 2025

[359] We note that this measure was endorsed by the NQF under NQF #1536 at the time of adoption but has subsequently had its endorsement removed.

[360] The implementation was first delayed by 3 months—from January 1, 2014 to April 1, 2014, for the CY 2016 payment determination, via guidance issued December 31, 2013. Available at: *https://qualitynet.cms.gov/files/5d3792e74b6d1a256059d87d?filename=2013-40-OP.pdf*. Because of continuing concerns, on April 2, 2014, we issued additional guidance stating that we would further delay the implementation of the measure from April 1, 2014 to January 1, 2015 for the CY 2016 payment determination. Available at: *https://qualitynet.cms.gov/files/5d3793174b6d1a256059d8e3?filename=2014-14-OP,0.pdf*.

[361] McAlinden C, Gothwal VK, Khadka J, Wright TA, Lamoureux EL, Pesudovs K. A head-to-head comparison of 16 cataract surgery outcome questionnaires. Ophthalmology. 2011 Dec;118(12):2374–81. doi: 10.1016/j.ophtha.2011.06.008. Epub 2011 Sep 25. PMID: 21945088.

[362] McAlinden C, Gothwal VK, Khadka J, Wright TA, Lamoureux EL, Pesudovs K. A head-to-head comparison of 16 cataract surgery outcome questionnaires. Ophthalmology. 2011 Dec;118(12):2374–81. doi: 10.1016/j.ophtha.2011.06.008. Epub 2011 Sep 25. PMID: 21945088.

payment determination will provide facilities with sufficient time to provide staff training and operationalize the measure for successful reporting in the Hospital OQR program.

Comment: Many commenters did not support the requirement for mandatory reporting of OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery and cited concerns about the operational complexity of collection and sharing data for the measure across physicians and outpatient settings. Many commenters believed administering surveys and tracking responses for the OP–31 measure would be burdensome. Specifically, many commenters were concerned that EHR systems were not compatible across physicians and outpatient settings, and were concerned by the potential burden their clinics and staff might face in extracting and sharing patient data. Several commenters were also concerned that requiring OP–31 would increase reporting burden during the ongoing COVID–19 pandemic and asked CMS to delay implementation.

Response: We thank the commenters for their input, and we acknowledge their concerns. We highly encourage hospitals, ophthalmologists, and other clinicians to actively and routinely engage in exchanging information to better communicate and coordinate the care of patients to promote quality of care. However, we acknowledge the complexity of administering and sharing data for OP–31 across different settings. In response to these concerns, we are finalizing the requirement to report the OP–31 measure beginning with the CY 2025 reporting period/CY 2027 payment determination instead of our originally proposed data collection beginning with the CY 2023 reporting period. We believe the 2-year extension will provide facilities with sufficient time for clinics and staff to address potential issues with extracting and sharing patient data. The 2-year extension will also allow facilities to prepare and update systems and technology, and prevent additional reporting burden during the COVID–19 pandemic.

Comment: A few commenters raised concerns with measure specifications, especially the lack of specificity around administration of the survey to ensure consistency between the pre- and post-operative surveys as well as comparability of the measure across hospitals. Several commenters requested additional guidance and education from CMS regarding measure specifications and survey instruments. Several commenters expressed their belief that this measure would be better suited to the Physician Quality Reporting System as it was developed as a physician-level measure. A few commenters expressed concern and confusion about administering a 90-day post-op examination. One of the commenters disagreed with the use of the study cited, noting that it reviewed responsiveness of different questionnaires and not comparison of agreement across different questionnaires. One commenter believed that surveys would have a low response rate and that results would not be reliable.

Response: We thank commenters for their feedback. We recognize commenters' concerns related to the measure specifications. However, we continue to believe the assessment of the McAlinden et al. study demonstrated that the use of different surveys did not result in inconsistencies [363] and we maintain that it is appropriate for inclusion in the Hospital OQR Program measure set. We also acknowledge that this measure has been tested at the physician-level and not the facility-level. We would like to clarify, in response to concerns about the administering a 90-day post-op examination, OP–31 is based on a patient survey to assess visual function and not a post-op examination, which tests for visual acuity. We reiterate our belief that OP–31 provides a valuable opportunity for patient feedback on visual function outside of the clinical setting.

Comment: Several commenters believed OP–31 has a limited use in evaluating patient improvement. A few commenters noted that cataract operations already have high rates of success. A few commenters noted that cataract surgeries are performed for other medical reasons beyond improving visual function. One commenter noted its belief that there is not just one measure that can be used to assess improved visual function.

Response: We thank commenters for their input. However, even if cataract procedures have high rates of success, this does not preclude facilities from reporting on OP–31 or continuously working to improve patient outcomes. We agree with the commenters that there is no one measure that can assess all possible medical needs and possible visual function outcomes; however, we continue to believe that OP–31 is a valuable and appropriate measure to close the gap for a high impact, frequently performed procedure.

After consideration of the public comments we received, we are finalizing the proposal to require OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery with modification. To address commenters' concerns, we are finalizing to require OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2025 reporting period/CY 2027 payment determination, instead of our originally proposed data collection beginning with the CY 2023 reporting period. We believe the 2-year extension from our originally proposed timeline of the CY 2023 reporting period/CY 2025 payment determination will provide facilities with additional time to implement coordination strategies between the surgeon and the ophthalmologist, to provide staff training, and operationalize the measure for successful reporting in the Hospital OQR Program.

6. Summary of Previously and Newly Finalized Hospital OQR Program Measure Sets

a. Summary of Previously and Newly Finalized Hospital OQR Program Measure Set for the CY 2023 Payment Determination

We refer readers to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86180 through 86181) for a summary of the previously adopted Hospital OQR Program measure set for the CY 2023 payment determination and subsequent years. As discussed previously, we are finalizing adoption of the Breast Cancer Screening Recall Rates measure in this final rule for the CY 2023 payment determination and subsequent years (OP–39). Table 63 summarizes the previously and newly finalized Hospital OQR Program measure set for the CY 2023 payment determination:

BILLING CODE 4120–01–P

[363] McAlinden C, Gothwal VK, Khadka J, Wright TA, Lamoureux EL, Pesudovs K. A head-to-head comparison of 16 cataract surgery outcome questionnaires. Ophthalmology. 2011 Dec;118(12):2374–81. doi: 10.1016/j.ophtha.2011.06.008. Epub 2011 Sep 25. PMID: 21945088.

TABLE 63: Hospital OQR Program Measure Set for the CY 2023 Payment Determination

NQF #	Measure Name
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-39: Breast Cancer Screening Recall Rates

† We note that NQF endorsement for this measure was removed.

* OP-31 measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947). In this final rule with comment period, we are finalizing mandatory reporting of this measure beginning with the CY 2023 reporting period/CY 2025 payment determination and for subsequent years.

b. Summary of Previously and Newly Finalized Hospital OQR Program Measure Set for the CY 2024 Payment Determination

Table 64 summarizes the previously and newly finalized Hospital OQR Program measure set for the CY 2024 payment determination, which includes the COVID–19 Vaccination Coverage Among HCP measure (OP–38):

TABLE 64: Hospital OQR Program Measure Set for the CY 2024 Payment Determination

NQF #	Measure Name
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-39: Breast Cancer Screening Recall Rates
None	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel

† We note that NQF endorsement for this measure was removed.

* OP-31 measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

c. Summary of Previously and Newly Finalized Hospital OQR Program Measure Set for the CY 2025 Payment Determination

Table 65 summarizes the previously and newly finalized Hospital OQR Program measure set for the CY 2025 payment determination, which includes the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM (OP–40) and removal of the OP–2 and OP–3 measures, and voluntary reporting of OAS CAHPS measures (OP–37a–e):

TABLE 65: Hospital OQR Program Measure Set for the CY 2025 Payment Determination

NQF #	Measure Name
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery***
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff*
None	OP-37b: OAS CAHPS – Communication About Procedure*
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery*
None	OP-37d: OAS CAHPS – Overall Rating of Facility*
None	OP-37e: OAS CAHPS – Recommendation of Facility*
None	OP-39: Breast Cancer Screening Recall Rates
None	OP- 38: COVID-19 Vaccination Coverage Among Health Care Personnel
None	OP-40: ST-Segment Elevation Myocardial Infarction (STEMI) eCQM**

† We note that NQF endorsement for this measure was removed.

* In this final rule with comment period, we finalizing voluntary reporting beginning with the CY 2023 reporting period/CY 2025 payment determination; and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

** The STEMI eCQM (OP-40) was proposed in the CY 2022 OPPS/ASC proposed rule (86 FR 42244), beginning with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination and for mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years. We refer readers to section XV.B.4.c. of the preamble of the CY 2022 OPPS/ASC proposed rule and of this final rule with comment period rule for more detail on finalizing adoption of this measure.

d. Summary of Previously and Newly Finalized Hospital OQR Program Measure Set for the CY 2026 Payment Determination and Subsequent Years

Table 66 summarizes the previously and newly finalized Hospital OQR Program measure set for the CY 2026 payment determination and subsequent years, which includes the mandatory reporting of the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM (OP–40) and the requirement of the OAS CAHPS measures (OP–37a–e):

TABLE 66: Hospital OQR Program Measure Set for the CY 2026 Payment Determination and Subsequent Years

NQF #	Measure Name
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff
None	OP-37b: OAS CAHPS – Communication About Procedure
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery
None	OP-37d: OAS CAHPS – Overall Rating of Facility
None	OP-37e: OAS CAHPS – Recommendation of Facility
None	OP-39: Breast Cancer Screening Recall Rates
None	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel
None	OP-40: ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

† We note that NQF endorsement for this measure was removed.

*OP-31 measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

BILLING CODE 4120–01–C

7. Hospital OQR Program Measures and Topics for Future Considerations

a. Request for Comment on Potential Adoption of Future Measures for the Hospital OQR Program

We seek to adopt a comprehensive set of quality measures for widespread use to inform decision-making regarding care and for quality improvement efforts in the hospital outpatient setting. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083 through 86110), under the OPPS we finalized the elimination of the Inpatient Only (IPO) list over a 3-year transitional period, beginning with the removal of approximately 300 primarily musculoskeletal-related services, with the list to be completely phased out by CY 2024.[364] As discussed in section IX. of the CY 2022 OPPS/ASC proposed rule (86 FR 42155) and section IX. of this final rule with comment period, we have continued to receive stakeholder requests to reconsider the elimination of the IPO list, to reevaluate services removed from the IPO list due to safety and quality concerns, and to, at a minimum, extend the timeframe for eliminating the list. After further consideration and review of the additional feedback from stakeholders, we believe that the timeframe we adopted for removing services from the IPO list does not give us a sufficient

[364] Centers for Medicare & Medicaid Services. (2020, December 2). CY 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS–1736–FC). Retrieved from *www.cms.gov/newsroom*: *https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0*.

opportunity to carefully assess whether a procedure can be removed from the IPO list while still ensuring beneficiary safety. In the CY 2022 OPPS/ASC proposed rule (86 FR 42155), for CY 2022, we proposed to halt the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021, we proposed to add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022.

However, as technology and surgical techniques advance, services will continue to transition off of the IPO list, becoming payable in the outpatient setting. We recognize that there may be a need for more measures that inform decision-making regarding care and for quality improvement efforts, particularly focused on the behaviors of services that become newly eligible for payment in the outpatient setting. In light of this, in the CY 2022 OPPS/ASC proposed rule (86 FR 42251), we sought comment on potential future adoption of measures that would allow better tracking of the quality of care for services that transition from the IPO list and become eligible for payment in the outpatient setting.

Therefore, we invited public comment on the potential future adoption of measures for our consideration that address care quality in the hospital outpatient setting given the transition of procedures from inpatient settings to outpatient settings of care.

We received comments on these topics and provide a summary of these comments below.

Comment: Many commenters offered suggestions in response to the Request for Comment on potential adoption of future measures in the Hospital OQR program. Several commenters encouraged CMS to work with stakeholders to identify a balanced set of high-quality, safe, and patient-centered measures that would be appropriate and useful across care settings particularly as procedures transition from the inpatient only list to outpatient settings. The commenters recommended that the measures should also address reporting challenges before proposing to adopt new measures into the OQR program. Several commenters believed CMS should explore additional measures addressing nutrition, breast cancer screening and diagnostic exams, structural equity related to disparity impact and the development of service-specific quality measures. One commenter also strongly recommended that CMS align with Leapfrog and its purchaser constituency by publicly reporting data in a way that puts the needs of consumers first.

Response: We thank commenters for their feedback. We will continue to work with stakeholders and take recommendations into consideration as we determine future updates to the Hospital OQR measure set. We will also explore the program need and feasibility of the commenters' measure recommendations as we consider measures for inclusion in future rulemaking.

Comment: A few commenters recommended that CMS should focus on developing Patient Reported Outcome (PROs) and patient experience measures to gather feedback directly from the patient without interpretation from a third-party source. Commenters stated that these measures can be broadly applied across the surgical domain and other procedures. Furthermore, they believed that prioritizing measures that focus on patients' feeling of inclusivity and developing patient reported metrics of inclusion in the care process is also an important step in addressing systemic bias in health care delivery.

Response: We appreciate the commenters' recommendations. We believe in the importance of patients having a greater role in their healthcare decision making. Accordingly, placing an emphasis on PRO measures directly aligns with our goals to modernize and drive value-based care. We will consider commenters' recommendations as we gather information for future rulemaking efforts.

Comment: Many commenters recommended that CMS consider adopting measures that are currently in the ASCQR Program measure set into the Hospital OQR Program's measure set. The measures commenters recommended for inclusion were: ASC–1, ASC–2, ASC–3, ASC–4, ASC–13, and ASC–14. Commenters noted that moving to adopt measures similar to these in the Hospital OQR Program would increase the alignment of measures between the Hospital OQR and ASCQR Programs and would allow consumers more opportunities to compare quality and safety across settings of care.

Additionally, a few commenters suggested that CMS should consider adopting the Toxic Anterior Segment Syndrome (TASS) measure and the Ambulatory Breast Procedure Surgical Site Infection Outcome Measure in the Hospital OQR Program.

Lastly, one commenter suggested that CMS should consider measures that focus on access to surgical care. The commenter suggests that these measures can provide information on whether patients gained timely access to a surgeon when/if they needed surgery.

Response: We thank the commenters for this valuable feedback. We recognize the need to consider measures that enhance quality improvement efforts moving forward. We also continue to explore ways to address measure gaps, reduce burden and increase efficiency through alignment and streamlining our programs. The information provided in response to this request for comment may inform future Hospital OQR Program rulemaking.

b. Request for Comment on Potential Future Adoption and Inclusion of a Hospital-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)

As described in section XV.B.7.a. of the CY 2022 OPPS/ASC proposed rule (86 FR 42251), we sought comment on priorities for quality measurement in outpatient settings due to changes to the IPO procedure list (82 FR 59385 and 84 FR 61355) and the ASC covered procedures list (CPL) (84 FR 61388 and 85 FR 86146) announced in the CY 2021 OPPS/ASC final rule with comment period.

We also requested comment on the potential future adoption of a respecified version of a patient-reported outcome-based performance measure (PRO–PM) for two such procedures—elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA), which were removed from the IPO list effective with CY 2020 and CY 2018, respectively. We recently solicited public comment on the potential future inclusion of a Hospital-Level Risk-Standardized Patient-Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (Hospital-Level THA/TKA PRO–PM (NQF #3559)) in the FY 2022 IPPS/LTCH PPS proposed rule for the inpatient hospital setting (86 FR 25589). We refer readers to the FY 2022 IPPS/LTCH PPS final rule for a summary of public comments (86 FR 45408). This measure reports the hospital-level risk-standardized improvement rate (RSIR) in patient-reported outcomes (PROs) following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older. Substantial clinical improvement is measured by achieving a pre-defined improvement in score on one of the two validated joint-specific PRO instruments measuring hip or knee pain and functioning: (1) The Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR)

for completion by THA recipients; and (2) the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients. Improvement is measured from the preoperative assessment (data collected 90 to 0 days before surgery) to the postoperative assessment (data collected 300 to 425 days following surgery). Improvement scores are risk adjusted to account for differences in patient case mix. Potential non-response bias in measure scores due to the voluntary nature of PROs is incorporated in the measure calculation with stabilized inverse probability weighting based on likelihood of response.

Currently, the volume of THA and TKA procedures performed is lower among HOPDs than in the inpatient setting. Given the relatively recent removal of TKA and THA from the IPO list, we expect that the volume of THA and TKA procedures will continue to increase in HOPDs, and that significant numbers of Medicare beneficiaries 65 and older will potentially undergo these procedures in the outpatient setting in future years.

We recognize that potential future adoption and implementation of a respecified version of the THA/TKA PRO–PM in the Hospital OQR Program would require sufficient numbers of procedures for each measured HOPD to ensure a reliable measure score. Additionally, implementing a THA/TKA PRO–PM would require providers to successfully collect pre- and post-operative PRO data for each procedure. Specifically, the inpatient THA/TKA PRO–PM discussed in the FY 2022 IPPS/LTCH PPS proposed rule would require a minimum of 25 cases with completed pre- and post-operative PRO data per hospital to ensure a reliable measure score. For more details on the inpatient THA/TKA PRO–PM, we refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25589) and the PROs Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

We will continue to monitor the number of THA and TKA procedures in the outpatient setting and when we believe there is a sufficient number of such procedures performed in these settings to reliably measure a meaningful number of facilities, we may consider expanding the PRO–PM to these settings. We also note that, as finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79764 through 79771), the Hospital OQR Program currently includes a Hospital Visits after Hospital Outpatient Surgery (OP–36) measure using claims data, which provides facilities with important information on patient outcomes for Medicare FFS beneficiaries following surgery at HOPDs and is publicly reported on CMS' *Care Compare* website (*https://www.medicare.gov/care-compare/*). The measure calculates a facility-specific risk-standardized hospital visit ratio within 7 days of hospital outpatient surgery, and has as outcomes of interest unplanned hospital admissions, ED visits, and observation stays thereby providing valuable quality information as these procedures are increasingly conducted as outpatient surgeries.

As described in our Meaningful Measures 2.0 Framework, we aim to promote better collection and integration of patients' voices by developing PRO measures as an additional tool for measuring and improving quality. Given the unique challenges and opportunities for PRO–PMs for THA and TKA procedures in the outpatient setting, we invited public comment on the potential future adoption of a respecified version of PRO measures for elective THA/TKA PRO–PM for the Hospital OQR Program in the CY 2022 OPPS/ASC proposed rule (86 FR 42252). Specifically, we invited public comment on the following:

- Input on the mechanism of PRO data collection and submission, including anticipated barriers and solutions to data collection and submission.
- Usefulness of having an aligned set of PRO–PMs across settings where elective THA/TKA are performed, that is, hospital inpatient setting, hospital outpatient departments, and ASCs for patients, providers, and other stakeholders. Specifically, usefulness and considerations for a hospital that performs both inpatient and outpatient elective THA/TKAs.
- Considerations unique to THA/TKAs performed in the hospital outpatient setting such as the volume of procedures performed or the measure cohort, outcome, or risk adjustment approach.

We received comments on these topics.

Comment: Many commenters supported inclusion of a Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) measure in the OQR program. As these procedures move from inpatient to outpatient settings, commenters noted it was important to monitor quality outcomes and publicly report results. Additionally, commenters stated that the proposed measure is aligned with patient values, being presented in a manner that is easy to understand. Commenters supported use of the HOOS, JR and the KOOS, JR as they are a widely used and less burdensome subset of the HOOS and KOOS surveys.

Response: We thank the commenters for their support of the potential future adoption of a respecified version of PRO measures for elective THA/TKA PRO–PM for the Hospital OQR Program.

Comment: Several commenters expressed concern regarding data collection burden. Commenters noted the increasing reporting threshold for hospitals voluntary participating in PRO collection in the Comprehensive Care for Joint Replacement (CJR) Model made it difficult for participants to meet the threshold. These commenters encouraged CMS to consider whether a lower rate of response is sufficient for measuring performance and asked that CMS cite specific reasons for the thresholds. A few commenters also raised concerns about patient burden, noting that completing patient-reported outcome surveys is burdensome for patients and may compete with other surveys, such as the OAS CAHPS Survey. Although commenters felt it was beneficial to have multiple options for collecting patient data, one commenter shared that their facility still struggled to collect patient-reported outcomes data despite using different modes that best fit their patient population.

Response: We thank the commenters for their feedback and would like to clarify the reporting thresholds. Through the CJR final rules (80 FR 73273 and 86 FR 23496), we finalized a data submission requirement that strategically increased with each performance year. To be successful, a hospital needed to submit PRO data for 50 percent or 50 eligible procedures in the first year of the Model. By performance year 8, hospitals will need to submit PRO data for 90 percent or 500 eligible procedures to be successful. The incremental increase over time allows hospitals to gradually build up their infrastructure and processes for collecting and storing data. While patient-reported outcome-based performance measures require providers to integrate data collection into clinical workflows, this integration provides opportunity for PROs to inform clinical decision making and benefit patients by

engaging them in discussions about potential outcomes.

We do not expect this PRO–PM to contribute to survey fatigue or to negatively impact other PRO–PMs. The Patient-Reported Outcome Measure (PROM) instruments used to calculate pre- and postoperative scores for this THA/TKA PRO–PM were carefully selected, with extensive stakeholder input, to be low burden for patients. We appreciate the feedback regarding challenges experienced in collecting PRO data; we encourage providers to incorporate data collection approaches that make PRO survey responses available to patients and providers for clinical decision making, for increased patient investment in PRO response.

Comment: A few commenters recommended using the American Joint Replacement Registry (AJRR) for implementation, citing that participation in the AJRR is a requirement for certification as a center of excellence by The Joint Commission. The commenters felt that using the AJRR would allow facilities to pool their resources for lowest costs. They also noted that as the AJRR incorporates Medicare Administrative Data for populating the database, its use would allow for robust risk adjustment, improved research, and independent reporting for participating facilities to normalize quality. Commenters noted that implementation through the AJRR infrastructure would be efficient for providers while minimizing duplication of reporting.

Response: We appreciate commenters' recommendations regarding the AJRR and we will consider the feasibility and appropriateness of using this registry for future implementation if we proceed with development of an HOPD THA/TKA PRO–PM. We agree that leveraging existing resources, such as registries, will help decrease data collection burden.

Comment: A few commenters provided feedback on differences related to having a joint replacement in the inpatient versus the outpatient setting. Specifically, these commenters noted that patients who undergo joint replacement in the inpatient setting tend to be sicker and more complex, which could result in an inappropriate comparison of quality amongst inpatient settings and outpatient settings. Commenters encouraged CMS to take this into consideration when developing a risk-adjustment strategy. Commenters also noted that caregiver support plays an important role in patient outcomes for procedures performed in the outpatient setting. Commenters also noted that it may be challenging for outpatient facilities to meet the minimum reporting threshold. To alleviate cohort concerns, one commenter encouraged CMS to consider implementing this measure with a three-year measurement period and to include all patients ages 18 and older.

Response: We thank commenters for their insights on the differences between inpatient and outpatient settings. With regards to facilities' ability to meet the reporting threshold, we agree that there must be a sufficient number of procedures in these settings to reliably measure a meaningful number of facilities, and we anticipate an increase in the number of THA/TKA procedures performed in the outpatient setting in future years. We will continue to monitor the cohort specification (including age) and the number of procedures captured during the specified measurement period to ensure meaningful measure results can be calculated. We appreciate the commenters' insight on the differences in patient complexity across different care settings, the need for having support at home, and the impact it may have on risk adjustment. We will continue to take this into consideration if we move forward with respecifying the measure for use in the HOPD setting. Any proposals to implement the measure will be announced through future rulemaking.

Comment: A few commenters expressed concern about the risk adjustment strategy for the measure. Commenters noted the risk adjustment model does not include a variable for Medicare dual eligibility status, nor does it take into consideration a patient's spoken language and other social risk factors that could impact survey completion. Commenters noted that PRO–PMs have the potential to provide valuable insights into health care disparities related to lower extremity arthroplasty and encouraged CMS to further stratify the results by additional social risk factors.

Response: We thank the commenters for their concern and would like to clarify the risk adjustment approach. For the development of the hospital measure, we assessed the impact of Medicare dual eligibility, the Agency for Health Research and Quality (AHRQ) socioeconomic status (SES) Index (socioeconomic status), and non-white race. The addition of each of these three social risk variables provided no statistically significant change to the risk model performance, variable coefficients, or the model outcome. As such, these variables were not included in the hospital risk model. These social risk variables were, however, statistically significantly associated with response to PRO surveys—whether patient-reported outcomes were obtained for patients undergoing primary elective THA/TKA—and so were included in the calculation of stabilized inverse probability weights used to account for potential response-bias. These variables, along with other social risk variables that may become available over time, will be reassessed as part of the respecification process if we proceed with developing an HOPD version of the measure as part of CMS' commitment to improving health equity.

Comment: A few commenters provided feedback for developing and implementing patient-reported outcomes. One commenter encouraged CMS to collect multi-stakeholder input throughout the development process. In addition to the KOOS, one commenter recommended the visual analog scale (VAS), and mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (EQ–5D–3L) scales. Lastly, a commenter recommended incentivized, phased implementation as hospitals who were not part of the CJR Model will need to build up infrastructure to support patient-reported outcome measures.

Response: We thank commenters for their feedback. As part of the inpatient hospital measure development process, the measure developer engaged extensively with technical expert panels and patient working groups to obtain feedback on key measure decisions. We thank the commenter for their suggestion to utilize an incentivized, phased implementation approach. We will continue to engage with stakeholders around these issues of additional survey instruments, phased implementation, and infrastructure improvements during any future development or implementation of an outpatient version of this measure, which would also be announced through notice and comment rulemaking.

Comment: A few commenters recommended measuring patient-reported outcomes at the provider-level as the provider has a strong influence on outcomes and a more direct relationship with the patient.

Response: We thank commenters for their recommendation to measure patient-reported outcomes at the clinician-level. Any future proposals to implement such a measure will be announced through notice and comment rulemaking.

Comment: A few commenters did not support the inclusion of a Risk-Standardized Patient Reported Outcomes Measure Following Elective

Primary THA/TKA measure in the OQR program. They cited the burden of collecting patient-reported outcomes data as the reason for not supporting this measure. Another commenter noted that although the procedures were removed from the IPO List, they did not agree that there will be a shift to the HOPD setting. The commenter questioned the validity of patient-reported outcomes data, noting that because a patient did not improve as he/she expected after surgery does not mean the patient did not receive quality care from the hospital. The commenter stated that determining clinical improvement after joint replacement is best determined by the orthopedist who is caring for the patient both pre- and post-procedure.

Response: We reiterate that the PROM instruments that are used to calculate pre- and postoperative scores for this THA/TKA PRO–PM were carefully selected, with extensive stakeholder input, to be low burden for patients and to capture information clinicians deemed essential to understanding response to THA/TKA. We believe that patient-reported outcome-based performance measures provide critical quality information and reflect outcomes that are meaningful to patients. Between January 1, 2018 and September 30, 2020, 264,997 total hip and/or total knee arthroplasties were performed in the outpatient setting. Developing a patient-reported outcomes measure for the Hospital OQR program would ensure these procedures benefit patients undergoing surgery by achieving meaningful improvement. The hospital-level measure was developed with considerable input from stakeholders including patients and orthopedic surgeons. In addition to the patient-reported outcome-based performance measure, CMS publicly reports results related to hospital readmission and complications following these procedures in the inpatient setting and the Hospital Visits after Hospital Outpatient Surgery (OP–36) measure covers these procedures in the outpatient setting.

Comment: One commenter recommended CMS consider measures that evaluate patient and caregiver engagement in decision-making, outcome measures that assess pain and functional status 3, 6, and 9-months post-procedure, and timely public reporting of comparative quality information about surgeons, surgical facilities, rehabilitation services, and home health services.

Response: We appreciate the commenter's recommendations regarding patient engagement, follow-up period, and public reporting. We engaged patients and patient advocates throughout the development of the Hospital-Level THA/TKA PRO–PM (NQF #3559). We will continue to engage patients and patient advocates, as appropriate, if this measure is respecified for the HOPD setting. We agree that timely public reporting of quality information is important for informed patient decision-making.

We appreciate all of the comments submitted in response to this request for comment. These comments may inform future policy development.

c. Request for Comment on Potential Future Efforts To Address Health Equity in the Hospital OQR Program

(1) Introduction and Expansion of the CMS Disparity Methods to Hospital OQR Program Setting

Significant and persistent inequities in health care outcomes exist in the U.S.[365] Belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; and being near or below the poverty level, are often associated with worse health outcomes.[366 367 368 369 370 371 372 373] Such disparities in health outcomes are the result of number of factors, including social, economic, and environmental factors, but importantly for CMS programs, although not the sole determinant, negative experiences, poor access, and provision of lower quality health care can contribute to health inequities. For instance, numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[374 375 376 377 378 379] Readmission rates for common conditions in the Hospital Readmissions Reduction Program (HRRP) are higher for Black Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with congestive heart failure and acute myocardial infarction.[380 381 382 383 384] Studies have also shown that African Americans are significantly more likely than White Americans to die prematurely from heart disease and stroke.[385] The COVID–19 pandemic has further highlighted

[365] United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities.*

[366] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[367] Lindenauer PK, Lagu T, Rothberg MB, *et al.* Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013;346.

[368] Trivedi AN, Nsa W, Hausmann LRM, *et al.* Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014;371(24):2298–2308.

[369] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[370] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[371] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[372] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[373] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[374] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[375] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[376] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec;73(12):2107–15.

[377] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[378] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[379] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[380] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. Am Heart J. Aug 2011;162(2):254–261 e253.

[381] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

[382] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[383] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. Chronic obstructive pulmonary disease readmissions at minority-serving institutions. Ann Am Thorac Soc. Dec 2013;10(6):680–684.

[384] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[385] HHS. Heart disease and African Americans. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among Black, Latino, and Indigenous and Native American persons relative to White persons.[386] [387] As noted by the CDC, ''long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID–19.'' [388] One important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across our programs and policies.

We are committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care inequities.[389] For the purposes of the RFI in the CY 2022 OPPS/ASC PPS proposed rule (86 FR 42232), we used a definition of equity established in Executive Order 13985, issued on January 25, 2021, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; LGBTQ+ persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [390] We noted that this definition was recently established and provides a useful, common definition for equity across different areas of government, although numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Network Quality Improvement Organizations (QIN–QIOs); Federal, state, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity.[391]

We refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 42252) which summarizes our existing initiatives aimed at closing the equity gap in outcomes for Medicare beneficiaries, including the CMS Disparity Methods. The methods were finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42496 through 42500), and results are currently reported confidentially across six quality measures in the HRRP stratified by dual eligibility status. As described in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 42252), we are considering further expanding the confidential reporting to include measurement of racial and ethnic disparities for one measure in the Hospital IQR Program, the Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789).

We have developed two complementary disparity methods to report stratified measure results for outcome measures. The first method (the Within-Hospital Disparity Method) promotes quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors. This method also allows for a comparison of the magnitude of disparity across hospitals at a given point in time, so hospitals could assess how well they are closing disparity gaps compared to other hospitals. The second methodological approach (the Across-Hospital Disparity Method) is complementary to the first method and assesses hospitals' outcome rates for patients with a given risk factor, across facilities, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors. These methods were first confidentially reported for the inpatient setting in 2019 for the Pneumonia Readmission (NQF #0506) and Pneumonia Mortality (NQF #0468) measures, stratified dual eligibility for Medicare and Medicaid, and confidential reporting for hospitals has since expanded to include additional measures. For additional information on the two disparity methods, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407) and the 2020 Disparity Methods Updates and Specifications Report.[392] As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41599) and the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070), the two disparity methods do not place any additional collection or reporting burden on hospitals because social risk factor data are readily available in claims data.

We received high-level comments on CMS' larger aforementioned plans to address health equity in quality reporting programs.

Comment: Many comments provided general support for efforts to improve equity through quality improvement programs and payment policies but not specific to the measurement considerations in the OQR and ASCQR RFIs. Commenters had varied recommendations for advancing equity through measurement and payment programs. Comments included statements that while there are numerous social risk factors, it is critical to prioritize equity as an emergent issue for Black, Hispanic/Latino, Indigenous and Asian communities and noted that systemic racism, not race, is a social risk factor.

Commenters recommended expanding the portfolio of programs and resources to support the related work of health care providers including data analyses and quality improvement activities to bridge hospital-level efforts with post-acute and community-based programs and models to close health equity gaps. A commenter noted that there are inadequate healthcare-based solutions for addressing social determinants of health. Another stated that working to solve the problems requires federal leadership, and a major aspect of that leadership needs to be addressing the inequities in resources these hospitals experience that have helped lead to the health care disparities in the communities in question. One commenter recommended that CMS build programs for addressing inequities from existing efforts from the public and private sector.

[386] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[387] Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[388] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[389] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[390] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[391] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[392] *https://qualitynet.cms.gov/inpatient/measures/disparity-methods/methodology.*

A number of commenters recommended that CMS engage in a robust stakeholder engagement process to discuss the input that was received.

Finally, on the broader use of measures to address health equity, one commenter stated CMS should not use equity health care quality metrics to rank hospitals on health equity because it could create competition rather than collaboration, while another stated that it would be helpful to see the disparities reported at the national level.

Response: We appreciate the feedback provided by the commenters regarding additional approaches to improving health equity outside of the specific topics covered in our OQR and ASCQR health equity RFIs. We will take commenters' feedback into consideration in future policy development.

In the CY 2022 OPPS/ASC proposed rule (86 FR 42252), we sought comment on expanding our efforts to provide results of the disparity methods to promote health equity and improve healthcare quality. Specifically, we sought comment on the idea of stratifying the performance results in the hospital outpatient setting. We have identified six priority measures included in the Hospital OQR Program as candidate measures for disparities reporting stratified by dual eligibility:

- MRI Lumbar Spine for Low Back Pain (OP–8);
- Abdomen CT—Use of Contract Material (OP–10);
- Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (OP–13);
- Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (OP–32);
- Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy (OP–35); and
- Hospital Visits after Hospital Outpatient Surgery (OP–36).

To identify these measures, we considered evidence of existing disparities, procedure volume, and statistical reliability. For more information about these measures, we refer readers to the Hospital Outpatient Quality Reporting Specifications Manual available on the QualityNet website.[393] We sought public comment on potential future confidential reporting of the six aforementioned measures, as well as other potential measures described in section XV.B.4. of the CY 2022 OPPS/ASC proposed rule (86 FR 42238) and of this final rule with comment period, stratified by dual eligibility status, if technically feasible, adequately representative, and statistically reliable.

The Within- and Across-Facility Disparity Methods would be applied to the selected measures. The methods offer two different, but complementary metrics of a facility's disparity. The Within-Facility method reports a difference in performance for patient populations at a specific facility (where a score of zero indicates equal outcomes), while the Across-Facility method reports a risk-standardized rate for the measure for only the target population, which shows facilities how they compare to the national average.

(2) Additional Social Risk Factors

We are committed to advancing health equity by improving data collection to better measure and analyze disparities across programs and policies.[394] As we described earlier, we have been considering, among other things, expanding our efforts to stratify data by additional social risk factors and demographic variables, optimizing the ease-of-use of the results, enhancing public transparency of equity results, and building towards provider accountability for health equity. Following potential confidential reporting using dual eligibility as an indicator of social risk, we are exploring the possibility of further expanding stratified reporting to include race and ethnicity.

We refer readers to the ''Closing the Health Equity Gap in CMS Hospital Quality Programs'' section of the FY 2022 IPPS/LTCH PPS proposed rule which summarizes the existing challenges in accurately determining race and ethnicity in our administrative data, and the need for using advanced statistical methods for enhancing the accuracy of race and ethnicity disparity estimates (86 FR 25554). We also refer readers to the FY 2022 IPPS/LTCH PPS final rule for a summary of public comments (86 FR 45349).

As we stated in the ''Closing the Health Equity Gap in CMS Hospital Quality Programs'' section of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25554), because development of sustainable and consistent programs to collect demographic information related to health disparities, such as race and ethnicity, can be considerable undertakings, we recognize that another method to identify more accurate race and ethnicity disparities is needed in the short term. In working with our contractors, two algorithms have been developed to indirectly estimate the race and ethnicity of Medicare beneficiaries (as described further in the next section). We believe that using indirect estimation can help to overcome some of the current limitations of demographic information and enable timelier reporting of equity results until longer term collaborations to improve demographic data quality across the health care sector materialize. The use of indirectly estimated race and ethnicity for conducting stratified reporting does not place any additional collection or reporting burdens on facilities as these data are derived using existing administrative and census-linked data.

Indirect estimation relies on a statistical imputation method for inferring a missing variable or improving an imperfect administrative variable using a related set of information that is more readily available.[395] Indirectly estimated data are most commonly used at the population level (such as the hospital or health plan-level) where aggregated results form a more accurate description of the population than existing, imperfect data sets. For missing race and ethnicity information, these methods use a combination of other data sources which estimate self-identified race and ethnicity, such as language preference, information about race and ethnicity in our administrative records, first and last names matched to validated lists of names correlated to specific national origin groups, and the racial and ethnic composition of the surrounding neighborhood. Indirect estimation has been used in other settings to support population-based equity measurement when self-identified data are not available.[396]

As described previously, we have previously supported the development of two such methods of indirect estimation of race and ethnicity of Medicare beneficiaries. One indirect estimation approach developed by our contractor uses Medicare administrative data, first name and surname matching, derived from the U.S. Census and other sources, with beneficiary language preference, state of residence, and the

[393] *https://qualitynet.cms.gov/outpatient/specifications-manuals.*

[394] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[395] 2020 Disparity Methods Updates and Specifications Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/disparity-methods/methodology.*

[396] Institute of Medicine. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press. Available at: *https://www.ahrq.gov/sites/default/files/publications/files/iomracereport.pdf.*

source of the race and ethnicity code in Medicare administrative data to reclassify some beneficiaries as Hispanic or Asian/Pacific Islander (API).[397] In recent years, we have also worked with another contractor to develop a new approach, the Medicare Bayesian Improved Surname Geocoding (MBISG), which combines Medicare administrative data, first and surname matching, geocoded residential address linked to the 2010 U.S. Census data, applying both Bayesian updating and multinomial logistic regression to estimate the probability of belonging to each of the six racial/ethnic groups.[398]

The MBISG model is currently used to conduct the national, contract-level, stratified reporting of Medicare Part C & D performance data for Medicare Advantage Plans by race and ethnicity.[399] Validation testing reveals concordances between 0.88–0.95 between indirectly estimated and self-reported race and ethnicity among those who identify as White, Black, Hispanic, and API for the MBISG version 2.0 and concordances with self-reported race and ethnicity of 0.96–0.99 for these same groups for MBISG version 2.1.[400] [401] [402] The algorithms under consideration are considerably less accurate for individuals who self-identify as American Indian/Alaskan Native or multiracial.[403] Indirect estimation is a statistically reliable approach for calculating aggregate results for groups of individuals (such as the facility-level) and is not intended, nor being considered, as an approach for predicting the race and ethnicity of individuals.

Despite the high degree of accuracy of the indirect estimation algorithms under consideration there remains the small risk of introducing measurement bias. For example, if the indirect estimation is not as accurate in correctly estimating race and ethnicity in certain geographies or populations it could lead to some bias in the method results. Such bias might result in slight overestimation or underestimation of the quality of care received by a given group. We believe this risk of bias is considerably less than would be expected if stratified reporting were conducted using the race and ethnicity currently contained in our administrative data. Indirect estimation of race and ethnicity is envisioned as an intermediate step, filling the pressing need for more accurate demographic information for the purposes of exploring inequities in service delivery, while allowing newer approaches, as described in the next section, for improving demographic data collection to progress. We are interested in learning more about, and soliciting comments about, the potential benefits and challenges associated with measuring facility equity using indirect estimation to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.

(a) Improving Demographic Data Collection

Stratified facility-level reporting using indirectly estimated race and ethnicity would represent an important advance in our ability to provide accurate equity reports to facilities. However, self-reported race and ethnicity data remain the gold standard for classifying an individual according to race or ethnicity. The CMS Quality Strategy outlines our commitment to strengthening infrastructure and data systems by ensuring that standardized demographic information is collected to identify disparities in health care delivery outcomes.[404] Collection and sharing of a standardized set of social, psychological, and behavioral data by hospitals, including race and ethnicity, using electronic data definitions which permit nationwide, interoperable health information exchange, can significantly enhance the accuracy and robustness of our equity reporting.[405] This could potentially include expansion of stratified reporting to additional social risk factors, such as language preference and disability status, where accuracy of administrative data is currently limited. We are mindful that additional resources, including data collection and staff training may be necessary to ensure that conditions are created whereby all patients are comfortable answering demographic questions, and that individual preferences for non-response are maintained.

We note that facilities participating in the Medicare Promoting Interoperability Program must use CEHRT that has been certified to the 2015 Edition of health IT certification criteria as defined at 45 CFR 170.102. As noted earlier, the certification criterion for Demographics under the 2015 Edition (45 CFR 170.315(a)(5)) supports collection of data using both the OMB standards for collecting data on race and ethnicity as well as the more granular ''Race & Ethnicity—CDC'' standard. In the 2020 ONC 21st Century Cures Act final rule, ONC also adopted a new framework for the core data set which certified health IT products must exchange, called the USCDI (85 FR 25669). The USCDI incorporates the demographic data and associated code sets finalized for the 2015 Edition certification criteria.

As noted previously, ONC also finalized a certification criterion in the 2015 Edition which supports a certified health IT product's ability to collect social, psychological, and behavioral data (45 FR 170.315(a)(15)). However, this functionality is not included as part of the CEHRT required by the Medicare Promoting Interoperability Program. While the technical functionality exists to achieve the gold standard of data collection, we understand challenges and barriers exist in using the technologies with these capabilities.

We solicited comment on current data collection practices by facilities to

[397] Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

[398] Haas, A, Elliott, MN, Dembosky, JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res. 2019; 54: 13–23. *https://doi.org/10.1111/1475-6773.13099*.

[399] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting*.

[400] The Office of Minority Health (2020). Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage, The Centers for Medicare and Medicaid Services, (pg vii). *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting*.

[401] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting*.

[402] We note for readers that the statistics reported for the MBISG 2.0 model in the CY 2020 OPPS/ASC proposed rule were incorrectly described and should be disregarded. In this final rule with comment period we correct this sentence to read as follows: ''With respect to Asian and Pacific Islander, Black, Hispanic, and White Medicare beneficiaries, the MBISG 2.1 has 96–99 percent concordance with what Medicare beneficiaries themselves report when allowed a full set of response options.'' Source: MBISG 2.1 validation results performed under contract #GS–10F–0012Y/HHSM–500–2016–00097G. Pending public release of the 2021 Part C and D Performance Data Stratified by Race, Ethnicity, and Gender Report, available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting*.

[403] Haas, A, Elliott, MN, Dembosky, JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res. 2019; 54: 13–23. *https://doi.org/10.1111/1475-6773.13099*.

[404] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf*.

[405] The Office of the National Coordinator for Health Information Technology. United State Core Data for Interoperability Draft Version 2. 2021. Available at: *https://www.healthit.gov/isa/sites/isa/files/2021-01/Draft-USCDI-Version-2-January-2021-Final.pdf*.

capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), primary language, and disability status). Further, we are interested in potential challenges facing facility collection, on the day of service, of a minimum set of demographic data elements in alignment with national data collection standards (such as the standards finalized by the Affordable Care Act) [406] and standards for interoperable exchange (such as the USCDI incorporated into certified health IT products as part of the 2015 Edition of health IT certification criteria).[407] Advancing data interoperability through collection of a minimum set of demographic data collection, and incorporation into quality measure specifications, has the potential for improving the robustness of the disparity method results, potentially permitting reporting using more accurate, self-reported information, such as race and ethnicity, and expanding reporting to additional dimensions of equity, including stratified reporting by disability status.

(b) Solicitation of Public Comments

In the CY 2022 OPPS/ASC proposed rule (86 FR 42252), we sought comment on the possibility of expanding our current disparities methods to include reporting by race and ethnicity using indirect estimation. We also sought comment on the possibility of facility collection of standardized demographic information for the purposes of potential future quality reporting and measure stratification to permit more robust equity measurement. Additionally, we sought comment on the design of a Facility Equity Score for presenting combined results across multiple social risk factors and measures, including race/ethnicity and disability. Any data pertaining to these areas that are recommended for collection for measure reporting for a CMS program and potential public disclosure on *Care Compare* or successor website would be addressed through a separate and future notice-and-comment rulemaking. We plan to continue working with the Office of the Assistant Secretary for Planning and Evaluation, facilities, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

Specifically, we invited public comment on the following:

- The potential future application to the Hospital OQR Program measures of the two disparity methods currently used to confidentially report stratified measures in HRRP.
- The possibility of reporting stratified results confidentially in Facility-Specific Reports (FSRs) using dual eligibility as a proxy for social risk.
- The possibility of reporting stratified results using dual eligibility as the proxy for social risk publicly on *Care Compare* in future years.
- The potential future application of an algorithm to indirectly estimate race and ethnicity to permit stratification of measures (in addition to dual-eligibility) for facility-level disparity reporting until more accurate forms of self-identified demographic information are available.
- The possibility of facility collection, on the day of service, of a minimum set of demographic data using standardized and interoperable electronic health record standards.

We received comments on these program-specific topics to address health equity.

Comment: Many commenters expressed support for the potential future application of the two disparity methods to the Hospital OQR Program, noting appreciation for CMS' recognition of the importance of closing the health equity gap. Commenters noted the importance of addressing health equity gaps in the outpatient settings and of providing hospitals with detailed data on their patient's dual eligibility status to enable tracking as procedures shift from acute care to outpatient. A few commenters expressed support for confidential reporting of stratified results in facility specific reports as it would result in actionable data for quality improvement. Several commenters stressed the importance of continued stakeholder engagement in projects designed to address structural and socioeconomic barriers to health, particularly to help policymakers understanding current practice trends and data collection challenges. Other commenters also recommended engagement through advisory groups and subject matter experts to test and pilot the application of the disparity methods to the Hospital OQR program to thoughtfully scale initiatives and promote nationwide standardization. One commenter requested CMS communicate their goals for future application of the disparity methods and inquired whether the goals are for accountability or resource assessment.

Some commenters expressed concern with any potential administrative burden placed onto providers and requested time to implement data collection efforts. A few commenters noted that many contributors to health inequities and related disparities are outside of the control of the health care system. Two commenters urged CMS to invest resources for data collection and in software upgrading.

While several commenters supported the proposed six measures as high-priority for stratified reporting, several commenters recommended thoughtful consideration of measurement gaps in identifying measures to be stratified, in addition to quality outcome benchmarks being developed prior to stratifying overused measure to avoid unintended consequences. Several commenters also recommended additional measure types for future stratification from additional data sources, such as experience surveys, or measurement domains, such as resource utilization/cost, access to surgical care, time of diagnosis or those that consider referrals to specialty care from a primary care setting. One commenter requested procedure-specific disparity reporting related to endoscopy, chemotherapy, or outpatient surgeries. One commenter recommended considering reinstating some quality measures where performance is felt to already be high, and to stratify these by social risk factors to assess additional room for improvement.

Response: We appreciate the feedback provided by the commenters regarding the potential future application of the two disparity methods in the Hospital OQR Program. We continue to prioritize minimizing provider burdened in efforts to improve equity, and to ensure stakeholder involvement in all initiatives. Confidential reporting of the disparity methods for the proposed six measures would use existing administrative records to calculate facility-level results, and as such, the provider burden would be minimal. In the upcoming year, we intend to begin confidential reporting for a number of the aforementioned measures stratified by dual eligibility status, if technically feasible, adequately representative, and statistically reliable.

Comment: Many commenters were generally supportive of our health equity initiatives and provided helpful recommendations on improving disparity measurement. Two commenters recommended structural and process measures to drive health equity improvement. One commenter recommended stratification methodologies compare safety net

[406] *https://minorityhealth.hhs.gov/assets/pdf/checked/1/Fact_Sheet_Section_4302.pdf.*

[407] *https://www.healthit.gov/sites/default/files/2020-08/2015EdCures_Update_CCG_USCDI.pdf.*

systems solely with other safety net systems to allow for a fairer comparison between hospitals treating similar patients and that are subject to similar levels of available resources. One commenter noted that current hospital-specific reports are based on outdated data and suggested data should be timely.

One commenter recommended leveraging technology, such as machine learning and artificial intelligence (AI), to analyze quality-of-care and outcomes using both patient demographics and clinical data to identify and address disparities. One commenter, however, disagreed noting that bias can manifest in machine learning and artificial learning if the AI algorithm is trained with incomplete data, and recommended a framework to guide the development and validation of algorithms to reduce bias. One commenter provided examples of how their organization has developed a social determinants of health framework to facilitate implementation of robust interventions through multi-stakeholder engagement. Another commenter discussed a local program that leverages data-driven approaches to confront and overcome health disparities.

Response: We appreciate the feedback provided by the commenters regarding future potential approaches to investigate disparities in our quality programs, and analyze outcomes data, and agree that adequate attention must be paid to limit the potential for unintended consequences. We will take commenters' feedback into consideration in future policy development.

Comment: Several commenters supported the expansion of the CMS Disparity Methods beyond dual eligibility for the potential future application of an algorithm to indirectly estimate race and ethnicity in the Hospital OQR Program. A few commenters requested that stratification by race and ethnicity begin with confidential reporting, as it would allow healthcare organizations an opportunity to improve planning for needed services; understand patterns in access and outcomes for different patients; and engage in quality improvement for new policies to reduce disparities. Two commenters preferred any stratified data be publicly available to allow stakeholders to assess the diverse needs of different patient populations.

While some commenters acknowledged that it is important to understand disparity by race and ethnicity, several commenters noted concern with the validity of using race and ethnicity data identified through indirect estimation, adding that it could lead to misleading results and introduce measurement bias. Three commenters noted concern with the use of first and last names to impute data as the results may be unreliable due to the various naming conventions commonly, noting that some beneficiaries, women or children in particular, may take the name of their husband or father, or an adopted individual may take their adoptive family's surname. Another commenter raised concerns with the use of the proposed indirect estimation MBISG approach, sharing an opinion that this method may raise questions about informed consent and that if the approach were to measure smaller racial/ethnic groups it may lose accuracy. Another commenter suggested that the existing limitations in using race-estimation algorithms outweigh the potential benefit of their use. Another commenter noted concern with the application of the indirect estimation of race and ethnicity data to MIPS measures due to the different levels of measurement, adding that imputed data can only be attributed to groups, while measures are often at the patient- or encounter-level. Several commenters did not support the confidential reporting of measure results by race and ethnicity as there was concern with the accuracy and actionability of the data. Three commenters did not support the use of indirect estimation of ethnicity and race in public reporting, however two commenters supported use in confidential reporting.

A few commenters recommended that CMS pursue standardized collection of race and ethnicity since there variation exists in the race and ethnicity categories collected by institutions and suggested advisory stakeholder engagement to inform a unified approach. Some commenters recommended that standards include more granular information about race and ethnicity. Several commenters requested CMS indicate short-term and long-term objectives for stratification by race and ethnicity to reduce inequities through heath care payment and delivery. One commenter suggested that the use of place-based risk factors may be a better approach. Another stated it was important that hospitals have the opportunity to address self-identified inaccuracies and a process to appeal data and outcomes.

Response: We appreciate the feedback provided by the commenters regarding stratification by race and ethnicity, the use of a model to estimate patient race and ethnicity and expanded disparity stratification. We will take commenters' feedback into consideration in future policy development.

We are sensitive to the concerns raised by stakeholders about indirect estimation. As referenced in the CY 2022 OPPS/ASC proposed rule (86 FR 42018) and summarized in the FY 2022 IPPS final rule (86 FR 25070), the Medicare program does not directly collect information from beneficiaries on race and ethnicity, instead relying on data collected by the Social Security Administration. A number of barriers contribute to this information being insufficiently accurate to examine hospital-level disparities. For example, prior to 1980, only three categories (White, Black, and Other) were available for individuals to self-report race, and respondents were not able to indicate other identities such as Asian, American Indian/Alaska Native, Hispanic, or Pacific Islander. As a result of these constrained response options, many current beneficiaries may not have had the opportunity to accurately self-report their race and ethnicity. Although we have undertaken significant efforts to update incorrect race and ethnicity information many inaccuracies remain limiting our ability to measure disparities.

In recent years we have sponsored the development of two indirect estimation algorithms, both intended to correct and improve administrative information on race and ethnicity. Indirect estimation methods such as these can generally be used in two different ways: (a) To estimate race/ethnicity in the absence of self-reported data; or (b) to improve administrative data in which beneficiaries provided a self-report of race/ethnicity but were not permitted a full set of response options (post-1980). While there is evidence supporting the validity of both approaches, accuracy and performance is particularly high in situation (b), where indirect estimation allows the administrative variables to better match the responses people would give when permitted a full set of response options. The approach for indirect estimation we intend to apply is situation (b), which uses an algorithm to augment existing data to allow a constrained administrative self-reported variable to better match what Medicare beneficiaries themselves may have chosen when given a comprehensive set of response options on race and ethnicity.

The Medicare Bayesian Improved Surname Geocoding Version 2.1 (MBISG 2.1) uses the original beneficiary self-report, but uses additional information supplied by Medicare beneficiaries and information about neighborhood composition, to make this variable

better match what Medicare beneficiaries themselves self-report when given a full set of response options. With respect to Asian and Pacific Islander, Black, Hispanic, and White Medicare beneficiaries, the improved version of the administrative variable has 96–99 percent concordance with what Medicare beneficiaries themselves report when allowed a full set of response options, matching much better than the original self-reported variable in which most Medicare beneficiaries were not allowed to indicate Asian, American Indian/Alaska Native, Hispanic, or Pacific Islander identities. The MBISG 2.1 also offers distinct advantages because it generates probabilities of identification in each racial and ethnic group for each beneficiary, rather than assigning a single identification.

The MBISG 2.1 incorporates multiple sources of information to develop racial and ethnic probabilities. In addition to the information on race and ethnicity which that person reported to the SSA, the model also considers the person's first and last name, the composition of the census block group where they live, and other demographic information that Medicare beneficiary shared. Through such a holistic approach, the MBISG 2.1 can make accurate comparisons between groups of Medicare beneficiaries regarding the quality of care received, including people whose surnames are common among several racial and ethnic groups, and people who changed their surnames upon marriage. The MBISG 2.1 is also designed to consider those who identify as Multiracial and allows measurement in Census categories that distinguish those who chose single or multiple racial identity, as well as considering endorsement of Hispanic ethnicity separately. Notably, we only intend to use the MBISG 2.1 to make inferences about aggregated groups at the hospital level, and do not intend to use it to make inferences about any single individual, validation studies indicate that these aggregate estimates further improve upon the higher predictive accuracy of the model.

We believe that use of statistical imputation models, such as the MBISG 2.1 will permit us to provide more accurate, less biased information on disparities in hospital outcomes when reported confidentially. We plan to report results confidentially to facilities in Spring 2022 where results are technically feasible, meaningful, and statistically reliable. Any potential future proposal to publicly display the disparity results on *Care Compare* would be made through future rulemaking. We are sensitive to the concerns raised by stakeholders and will continue to evaluate the validity of the readmission measures when stratified by indirect estimation during the confidential reporting period.

We appreciate the feedback provided by the commenters regarding measuring health equity in our hospital outpatient and ambulatory surgical center quality measurement programs. We will continue to take all concerns, comments, and suggestions into account in our future policies.

Comment: Several commenters supported the facility collection of patient demographics. Many commenters recommended healthcare workforce education regarding data collection to ensure accurate and culturally sensitive collection of patients' demographic information. Other commenters urged education to beneficiaries on the need to share sensitive and personal information and the use of such data. Three commenters recommended use of EHR capabilities to facilitate data collection and routinely collect race, ethnicity, and language preference data, noting that the use of these capabilities can reduce administrative burden on healthcare facilities. One commenter recommended CMS engage nurses to identify and capture demographics for data collection to address health equity. A few commenters encouraged alternative collection methods such as updating the common working file (CWF) or utilizing HIPAA transaction sets to capture race and ethnicity. Other commenters recommended development of additional billing codes for social needs and evaluation of existing social determinants of health (SDOH) billing codes and International Classification of Diseases, Tenth Revision (ICD–10) Z codes, which identify non-medical factors that may influence a patients' health status. Further, commenters recommended using screening tools such as the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) tool or the Accountable Health Communities Health-Related Social Needs Screening Tool developed by CMS.

Commenters urged CMS to expand data collection to include factors such as sexual orientation, gender identity, language preference, tribal membership, disability status, socioeconomic status (SES), education, social support, food security, transportation access, and housing stability to provide a more comprehensive assessment of health equity. A few commenters included the need for information on language spoken, health literacy, incarceration status and veteran status. Other commenters expressed support for expanding stratification to additional social risk factors and demographic variables, such as primary language, geographic location, socioeconomic status, gender identity, sexual orientation, age, and ability status. Additionally, a few commenters recommended CMS require data collection methods that rely only on self-reported data. Another commenter asserted that emerging evidence suggests that healthcare disparities may be rooted in lived experiences and recommended CMS include questions specific to experiences of certain racial or ethnic groups within the healthcare system, such as mistrust of the healthcare system and providers, experiences of microaggression and perceived discrimination or injustices. Additionally, a few commenters encouraged improvement of hospital data collection by mandating a minimum data collection threshold. Similarly, one suggested limiting the number of social risk factors collected to ensure consistent reliable data prior to expanding the number of factors. Others recommended CMS set reasonable goals and timelines for the collection of self-reported demographic data. Finally, a commenter suggested that CMS work with state Medicaid agencies to improve the consistency of data collection at the time of Medicaid enrollment and another noted unique challenges to collecting data from certain sub-populations of beneficiaries such as homeless patients.

Two commenters did not support an expanded data collection, noting concern with the burden and costs that would impact hospitals, or providers in QPP. Three commenters urged for alternative methods of capturing patient demographics via facility collection to reduce administrative burden on providers and encouraged leveraging of data in certified electronic medical records, adding that physicians should not have to invest resources for any modifications. A few commenters encouraged investment in interoperable and secure data infrastructure. One commenter suggested rather than health systems, payers such as CMS take the lead in collecting demographic data as a more efficient approach.

Several commenters urged CMS to develop information technology standards and consistent guidance across programs for the capture, use, and exchange of relevant data such as the use of electronic health records and FHIR standards. Three commenters recommended CMS adopt the Office of the National Coordinator for Health Information Technology's (ONC) 2015

Edition Health Information Technology Certification standards across all CMS quality programs including the Promoting Interoperability Program, to leverage existing infrastructures for data collection.

While supportive of collecting and utilizing demographic and SDOH data to measure and improve health equity, several commenters expressed concerns about protecting patient privacy. One of these commenters recommended CMS increase beneficiary education on the sharing of their sensitive health information with their providers. Another of these commenters asked that CMS address privacy considerations related to privacy, confidentiality and alignment with other federal standards related to data sharing and interoperability.

Response: We appreciate the feedback provided by the commenters regarding expanded demographic and social risk factor data collection. We will take commenters' feedback into consideration in future policy development.

Comment: We received mixed feedback from commenters about a potential facility equity score. A few commenters supported a facility equity score, noting a composite score is helpful to gauge disparities in large populations. One commenter noted that the composite equity score, however, depends on the comprehensiveness of the data and requires a broad spectrum of factors to avoid inaccuracies and undermining of the scoring methodology. One commenter recommended a patient-level equity score to identify patient populations that require additional services such as nutritional counseling, access to healthy foods, or transportation. Additional commenters suggested using tools such as the Health Equity Report Card or developing an SDOH report based on U.S Department of Health and Human Services (HHS') Health People 2030 framework. One commenter also suggested CMS consider the recommendations that identified by the American Hospital Association for improving care for vulnerable communities, such as including screening patients for social needs, offering navigation services to help patients access community services, and partnering with community stakeholders to align with local needs.

A majority of commenters did not believe a facility equity score would provide actionable information to the patients or hospitals and encouraged other mechanisms for health equity advancement be developed, such as further stratification of quality measures by race, ethnicity, and dual eligibility. Several commenters noted concern that a facility equity score may inadvertently obscure lower performances on quality measures or impact reimbursements of facilities with greater proportions of vulnerable populations. Other commenters were concerned with the accuracy of facility scores that use data which may not be uniformly collected across hospitals. One commenter requested local customization of the hospital health equity score that would allow an accurate reflection of hospital's commitment to its community, and a hospital-specific methodology, versus the application of the Medicare Advantage hospital health equity score.

Response: We appreciate the feedback provided by the commenters regarding the potential creation of a facility equity score. We will take commenters' feedback into consideration in future policy development.

Comment: Commenters also provided broad feedback to us around other approaches, beyond quality measurement, that we may undertake to ensure more equitable care for Medicare beneficiaries in the hospital outpatient setting. One commenter suggested CMS consider developing and implementing measures that are stratified by access to healthcare, access to primary care, and quality of care. Three commenters noted that many safety net systems operate with limited resources that can impact patient access to care, forcing patients to wait months for screening and prevention or advanced imaging, adding that to improve the care of this population both acute and primary care must improve care coordination and CMS must provide necessary resources.

Response: We appreciate the feedback provided by the commenters regarding equitable access to care in the outpatient setting. We will take commenters' feedback into consideration in future policy development.

8. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we modify the Hospital OQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet website at: *https://qualitynet.cms.gov/outpatient/specifications-manuals*. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59104 through 59105), where we changed the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019 and subsequent years, such that we will release a manual once every 12 months and release addenda as necessary. We did not propose any changes to these policies in the CY 2022 OPPS/ASC proposed rule.

In section XV.B.4. of the CY 2022 OPPS/ASC proposed rule (86 FR 42244), we proposed the adoption of eCQMs into the Hospital OQR Program measure set beginning with the CY 2023 reporting period. Therefore, we also proposed the manner to update the technical specifications for eCQMs. We proposed that the technical specifications for eCQMs used in the Hospital OQR Program would be contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update). The Annual Update and implementation guidance documents are available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/*. For eCQMs, we would generally update the measure specifications on an annual basis through the Annual Update which includes code updates, logic corrections, alignment with current clinical guidelines, and additional guidance for hospitals and EHR vendors to use in order to collect and submit data on eCQMs from hospital EHRs.

Hospitals would be required to register and submit quality data through the Hospital Quality Reporting (HQR) System (formerly referred to as the QualityNet Secure Portal). 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, for more information.

We received comments on these topics.

Comment: A few commenters supported our proposal, expressing agreement with the alignment of the Hospital OQR Program's eCQM technical specification updates with other quality reporting programs, specifically, the Hospital IQR Program.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing this proposal as proposed.

We also refer readers to section XIV. of the CY 2022 OPPS/ASC proposed rule (86 FR 42232) where we requested information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the FHIR standard (as described in that section).

9. Public Display of Quality Measures

a. Background

We refer readers to the CY 2009, CY 2014, and CY 2017 OPPS/ASC final rules with comment period (73 FR 68777 through 68779, 78 FR 75092, and 81 FR 79791, respectively) for our previously finalized policies regarding public display of quality measures. We did not propose any changes to these policies in the proposed rule.

b. Overall Hospital Quality Star Rating

In the CY 2021 OPPS/ASC final rule (85 FR 86182), we finalized a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Rating). We refer readers to section XVI. (''Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years'') of the CY 2021 OPPS/ASC final rule with comment period for details. We did not propose any changes to this policy in the proposed rule.

C. Administrative Requirements

1. QualityNet Account and Security Administrator/Security Official

a. Background

The previously finalized QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines, are described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109). We codified these procedural requirements at § 419.46(b) in that final rule with comment period. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86182), we finalized to use the term ''security official'' instead of ''security administrator'' to denote the exercise of authority invested in the role. The term ''security official'' would refer to ''the individual(s)'' who have responsibilities for security and account management requirements for a hospital's QualityNet account. This update in terminology did not change the individual's responsibilities or add burden. We did not propose any changes to this policy in the CY 2022 OPPS/ASC proposed rule.

b. Active Security Official Account and Maintenance Requirements for Data Submission

The previously finalized QualityNet security administrator (now referred to as a security official) requirements, including those for setting up a QualityNet account and the associated timelines, are described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72099) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74479), we indicated that hospitals would be required to maintain a current QualityNet security administrator (now referred to as a security official) for as long as the hospital participates in the Program. In the CY 2022 OPPS/ASC proposed rule (86 FR 42257), we clarified that failing to maintain an active QualityNet security official once a hospital has successfully registered to participate in the Hospital OQR Program will not result in a finding that the hospital did not successfully participate in the Hospital OQR Program. Again, we refer readers to requirements at § 419.46(b).

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519), and the CY 2019 OPPS/ASC final rule with comment period (83 FR 59103 through 59104) for requirements for participation and withdrawal from the Hospital OQR Program. We codified these requirements at § 419.46(b) and (c). We did not propose any changes to these policies in the proposed rule.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Submission Deadlines

We refer readers to the CYs 2014, 2016, and 2018 OPPS/ASC final rules with comment period (78 FR 75110 through 75111; 80 FR 70519 through 70520; and 82 FR 59439, respectively) where we finalized our policies for clinical data submission deadlines. We codified these submission requirements at § 419.46(d). The clinical data submission deadlines for the CY 2024 payment determination are illustrated in Table 67.

TABLE 67: CY 2024 Payment Determination*

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2022 (April 1 - June 30)	11/1/2022
Q3 2022 (July 1 – September 30)	2/1/2023
Q4 2022 (October 1 - December 31)	5/1/2023
Q1 2023 (January 1 - March 31)	8/1/2023

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

We did not propose any changes to these policies in the proposed rule.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2024 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form, manner, and timing for data submission requirements of chart-abstracted measures for the CY 2014 payment determination and subsequent years. We did not propose any changes to these policies in the proposed rule.

The following previously finalized Hospital OQR Program chart-abstracted measures will require patient-level data to be submitted for the CY 2023 payment determination and subsequent years:

- OP–2: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496); [408]

[408] In the CY 2022 OPPS/ASC proposed rule (86 FR 42237) we proposed to remove OP–2 beginning

- OP–3: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496); [409]
- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496); and
- OP–23: Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT Scan Interpretation Within 45 Minutes of ED Arrival (NQF #0661).

3. Claims-Based Measure Data Requirements for the CY 2024 Payment Determination and Subsequent Years

Currently, in addition to the proposed Breast Cancer Screening Recall Rates measure (OP–39), the following previously finalized Hospital OQR Program claims-based measures are required for the CY 2023 payment determination and subsequent years:

- OP–8: MRI Lumbar Spine for Low Back Pain (NQF #0514);
- OP–10: Abdomen CT—Use of Contrast Material;
- OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery (NQF #0669);
- OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539);
- OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy;
- OP–36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687); and
- OP–39: Breast Cancer Screening Recall Rates.[410]

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59106 through 59107), where we established a 3-year reporting period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy beginning with the CY 2020 payment determination and for subsequent years. In that final rule with comment period (83 FR 59136 through 59138), we established a similar policy under the ASCQR Program. We did not propose any changes to these policies in the proposed rule. We refer readers to section XV.B.4.b. of this final rule with comment period where we are finalizing a 3-year reporting period for the Breast Cancer Screening Recall Rates measure (OP–39).

4. Data Submission Requirements for the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures for the CY 2024 Reporting Period/CY 2026 Payment Determination and Subsequent Years

a. Background

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79792 through 79794) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures. In addition, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433), where we finalized a policy to delay implementation of the OP–37a–e OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (2018 reporting period) until further action in future rulemaking.

b. Form, Manner, and Timing for OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

As discussed in section XV.B.5.a. of this final rule with comment period, we are finalizing to begin data collection of five survey-based measures derived from the OAS CAHPS Survey beginning with voluntary data collection and reporting for the CY 2023 reporting period/CY 2025 payment determination,[411] followed by mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years. The OAS CAHPS Survey contains three OAS CAHPS composite survey-based measures and two global survey-based measures. In this section, we proposed requirements related to survey administration, vendors, and oversight activities.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79792 through 79794), we previously discussed the form, manner, and timing of this survey. In the CY 2022 OPPS/ASC proposed rule (86 FR 42258), we reaffirmed our approach to the form, manner, and timing which OAS CAHPS information will be submitted and proposed to add two additional data collection modes (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents),[412] beginning with voluntary data collection for the CY 2023 reporting period/CY 2025 payment determination and continuing for mandatory reporting for subsequent years. For more information about the modes of administration, we refer readers to the OAS CAHPS Survey website: *https://oascahps.org*. We reiterated our clarification from when we adopted these measures in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79773) that, when implemented, hospital outpatient departments that anticipate receiving more than 300 surveys would be required to either: (1) Randomly sample their eligible patient population; or (2) survey their entire OAS CAHPS eligible patient population. We also refer readers to section XVI.D.1.d. of this final rule with comment period where we are finalizing similar policies for the ASCQR Program.

(1) Survey Requirements

The data collection modes as currently specified for the survey include three administration modes: (1) Mail-only; (2) telephone-only; and (3) mixed mode (mail with telephone follow-up of non-respondents). We refer readers to the Protocols and Guidelines Manual for the OAS CAHPS Survey (*https://oascahps.org/Survey-Materials*) for materials for each mode of survey administration. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59433), we expressed interest in investigating the feasibility of offering the OAS CAHPS Survey using a web-based format. As a result, we designed a mode experiment to assess the impact of adding web-based survey administration. This mode experiment tested five administration modes with patients who receive outpatient surgical care: (1) Mail-only; (2) telephone-only; (3) web-only; (4) web with mail follow-up; and (5) web with a telephone follow-up. Data collection was completed in the fall of 2019. Response rates by mode in the experiment were: 35 percent (mail-only); 19 percent (telephone-only); 29 percent (web-only); 39 percent (web with mail follow-up);

with the CY 2023 reporting period/CY 2025 payment determination. We are finalizing this proposal in this final rule with comment period.

[409] In CY 2022 OPPS/ASC proposed rule (86 FR 42237), we proposed to remove OP–3 beginning with the CY 2023 reporting period/CY 2025 payment determination. We are finalizing this proposal in this final rule with comment period.

[410] We note that that we are finalizing our proposal as proposed for the inclusion of OP–39: Breast Cancer Screening Recall Rates into the Hospital OQR Program measure set.

[411] As stated in section XV.B.5.a. of this final rule with comment period, we note that National OAS CAHPS voluntary reporting program is independent of the Hospital OQR Program, but the submission process will otherwise remain unchanged. This proposal is intended to clarify that voluntary reporting of OAS CAHPS would begin as part of the Hospital OQR Program in the CY 2023 reporting period until mandatory reporting would begin in the CY 2024 reporting period/CY 2026 payment determination and for subsequent years, if both proposals are finalized.

[412] The two additional modes will be available as part of National OAS CAHPS voluntary reporting program in 2022.

and 35 percent (web with telephone follow-up).

Based on these results, in addition to the three previously established modes, in the CY 2022 OPPS/ASC proposed rule (86 FR 42258), we proposed to incorporate two more administration methods: (1) Mixed mode web with mail follow-up of non-respondents, and (2) mixed mode web with telephone follow-up of non-respondents. This would allow a total of five methods of survey administration for reporting beginning with voluntary data collection and reporting as part of the Hospital OQR Program for the CY 2023 reporting period/CY 2025 payment determination [413] and mandatory reporting for the CY 2024 reporting period/CY 2026 payment determination—the first year the survey would be required. We did not propose a purely web-based format at this time because the use of a web-based mode is included in the two mixed modes options being proposed and the purely web-based format would create response bias since not all patients have the ability to respond by web.

For all five proposed modes of administration as part of the Hospital OQR Program, we proposed that data collection must be initiated no later than 21-calendar days after the month in which a patient has a surgery or procedure at a hospital and completed within 6 weeks (42 days) after initial contact of eligible patient begins, beginning with voluntary reporting in the CY 2023 reporting period/CY 2025 payment determination and subsequent years. Under this proposal, hospitals, via their CMS-approved vendors (discussed in section XV.D.4.b.(2). of the CY 2022 OPPS/ASC proposed rule (86 FR 42259)), must make multiple attempts to contact eligible patients unless the patient refuses or the vendor learns that the patient is ineligible to participate in the survey. In addition, we proposed that hospitals, via their CMS-approved survey vendor, collect survey data for eligible patients using the established quarterly deadlines to report data to CMS for each data collection period unless the hospital has been exempted from the OAS CAHPS Survey requirements under the low volume exemption. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79774) where we previously established the low volume exemption, which exempts hospital outpatient departments with fewer than 60 survey-eligible patients during the ''eligibility period,'' (which is the calendar year before the data collection period), that submit the participation exemption request form, which would be made available on the OAS CAHPS Survey website (*https://oascahps.org*) on or before May 15 of the data collection year. As finalized previously, all exemption requests would be reviewed and evaluated by CMS (81 FR 79774). For hospitals that do not have an exemption, the submission deadlines would be posted on the OAS CAHPS Survey website (*https://oascahps.org*). Late submissions would not be accepted.

As discussed in more detail in this section, compliance with the OAS CAHPS Survey protocols and guidelines, including this monthly data collection requirement as part of each quarterly data submission, would be overseen by CMS or its contractor who would receive approved vendors' monthly submissions, review the data, and analyze the results. We previously finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79774) all data collection and submission for the OAS CAHPS Survey measures would be reported at the Medicare participating hospital level, as identified by its CCN. Once data collection and reporting become mandatory beginning with the CY 2024 reporting period as finalized in section XV.B.5.a of this final rule with comment period, all locations that offer outpatient services of each eligible Medicare participating hospital would be required to participate in the OAS CAHPS Survey finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79793) except for those that meet and receive an exception for having fewer than 60 survey-eligible patients during the year preceding the data collection period as finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79773). Therefore, the survey data reported using a Medicare participating hospital's CCN must include all eligible patients from all outpatient locations (whether the hospital outpatient department is on campus or off campus) of an eligible Medicare participating hospital; or if more than 300 completed surveys are anticipated, a hospital can choose to randomly sample their eligible patient population as finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79784).

In the CY 2022 OPPS/ASC proposed rule (86 FR 42259), we also proposed that survey vendors acting on behalf of hospitals must submit data by the specified data submission deadlines, which generally would be posted on the OAS CAHPS Survey website located at *https://oascahps.org/Data-Submission/Data-Submission-Deadlines*. If a hospital's data are submitted after the data submission deadline, it would not fulfill the OAS CAHPS Survey quality reporting requirements. Therefore, in regard to any OAS CAHPS Survey reporting, we would strongly encourage hospitals to be fully apprised of the methods and actions of their survey vendors—especially the vendors' full compliance with OAS CAHPS Survey administration protocols—and to carefully inspect all data warehouse reports in a timely manner.

We reiterate that the use of predictive or auto dialers in telephonic survey administration is governed by the Telephone Consumer Protection Act (TCPA) (47 U.S.C. 227) and subsequent regulations promulgated by the Federal Communications Commission (FCC) (47 CFR 64.1200) and the Federal Trade Commission. We refer readers to the FCC's declaratory ruling released on July 10, 2015 further clarifying the definition of an auto dialer, available at: *https://apps.fcc.gov/edocs_public/attachmatch/FCC-15-72A1.pdf*. In the telephone-only and mixed mode survey administration methods involving telephone, hospitals and vendors must comply with the regulations and any other applicable regulations. To the extent that any existing CMS technical guidance conflicts with the TCPA or its implementing regulations regarding the use of predictive or auto dialers, or any other applicable law, CMS would expect vendors to comply with applicable law.

We received comments on these topics.

Comment: A commenter supported the proposal that the CAHPS data collection must be ''initiated no later than 21-calendar days after the month in which a patient has a surgery or procedure at a hospital and completed within 6 weeks (42 days) after initial contact of eligible patient begins, beginning with voluntary reporting in the CY 2023 reporting period/CY 2025 payment determination and subsequent years.''

Response: We thank the commenter for its support.

Comment: A commenter recommended that CMS consider adopting ''real time surveys'' or surveys performed within 48 hours as a survey option for OAS CAHPS Survey.

[413] As stated in section XV.B.5.a. of the CY 2020 OPPS/ASC proposed rule, we note that the two modes (web with mail follow-up of non-respondents; and web with telephone follow-up of non-respondents) will be available beginning in CY 2022 for National OAS CAHPS voluntary reporting, and then if finalized, available as part of OQR Program's reporting beginning in the CY 2023 reporting period and subsequent years (86 FR 42258).

Response: Under the current guidelines, HOPDs can request to do continuous sampling to receive more ''real time'' feedback, which could include initiating their own surveys within 48 hours.

Comment: Many commenters supported the two additional survey administration modes taking advantage of web-based technology: Web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents. Among the reasons for support were the belief that these additional modes will enable providers to reach a larger patient population, to receive more and timelier information to improve patient experience, to reduce burden associated with this measure, and to provide greater flexibility for providers to collect data and patients to respond. A few commenters encouraged CMS to monitor the data and patient response rates, particularly of the two additional web-based survey modes, and data.

Response: We thank the commenters for their support. We agree that as we expand the use of additional OAS CAHPS Survey modes, it will be important to monitor data, patient responses and ensure that the OAS CAHPS Survey is refined as appropriate. We will continue to monitor and evaluate methods available to assess and collect patient experience feedback in a reliable manner.

Comment: Many commenters appreciated the proposal for the additional two new mixed mode options that include web-based collection, but expressed the belief that there needs to be a web-only or additional digital modes to reduce financial burden of the survey and make the survey easier for patients to complete. Several commenters recommended that CMS should permit a web-only survey administration mode and noted that web-only would likely be popular form of administration, has a better response rate and could achieve minimum surveys more efficiently than telephone only and would also reduce the financial burden of administration. One commenter specifically noted that these modes of survey distribution could help reach younger and minority populations.

Response: We agree that the web-based mode interactions with smart phones, email, texting and other electronic distribution create the potential for new and engaging ways to connect with patients, especially to traditionally underserved communities. We believe that the potential to expand and increase access to patient feedback is of the utmost importance and will continue to evaluate the potential refinement to methods of contact for the OAS CAHPS Survey. However, as we stated in the CY 2022 OPPS/ASC proposed rule (86 FR 42258), we did not propose a purely web-based format at this time because the purely web-based format would create response bias since not all patients have access and the ability to respond via website. Additionally, the use of a web-based mode is included in the two mixed modes options being proposed and we believe that providing the additional follow-up provides patients with a greater opportunity to respond to the OAS CAHPS Survey, if they so choose.

Comment: A few commenters expressed concern that patients may be confused by web-based surveys and CMS should ensure that patients understand the survey.

Response: We note that an objective of the OAS CAHPS Survey is to obtain data on a patient's experience of care received from a facility, specifically from an HOPD. While there is always potential that a patient gets confused, we believe that the OAS CAHPS Survey is focused on patients' experience of care received for their ambulatory surgery or procedure. A physician/surgeon who performs surgeries/procedures at a facility is a member of that facility with both rights and responsibilities. We believe it is the facility's responsibility to ensure that someone—whether the doctor, nurse, or other facility staff member—provide patients with information about preparing for their procedure, about the procedure itself, as well as what to expect following the procedure/surgery. Therefore, we believe it is appropriate to include these important communications with patients in the OAS CAHPS Survey and believe experience with the provider attributed to the facility is appropriate.

Further, we believe that the information provided in the OAS CAHPS Survey ''Instructions'' is sufficient to inform the patient regarding the purpose of the OAS CAHPS Survey and provides sufficient instruction and details for the patient to correctly identify and relate the survey to the facility and procedure that patient received. CMS began developing the Outpatient and Ambulatory Surgery Survey in 2012 using the principles and guidelines established by the Agency for Healthcare Research and Quality's (AHRQ) CAHPS program and AHRQ approved this instrument as a CAHPS Survey in February 2015.[414]

After consideration of the public comments we received, we are finalizing this proposal as proposed.

(2) Vendor Requirements

We did not propose any new vendor requirements in the CY 2022 OPPS/ASC proposed rule (86 FR 42018), but reiterate the vendor requirements finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79793 through 79794) to ensure that patients respond to the survey in a way that reflects their actual experiences with outpatient care, and is not influenced by the hospital. We finalized that hospitals must contract with a CMS-approved OAS CAHPS Survey vendor to conduct or administer the survey. We believe that a neutral third-party should administer the survey for hospitals, and it is our belief that an experienced survey vendor would be best able to ensure reliable results. CAHPS Survey-approved vendors are also already used or required in the following CMS quality programs: The Hospital IQR Program (71 FR 68203 through 68204); the Hospital VBP Program (76 FR 26497, 26502 through 26503, and 26510); the End Stage Renal Disease Quality Improvement Program (76 FR 70269 through 70270); the Home Health QRP (80 FR 68709 through 68710); and the Hospice QRP (80 FR 47141 through 47207).

Information about the list of approved survey vendors and how to authorize a vendor to collect data on a hospital's behalf is available through the OAS CAHPS Survey website at: *https://oascahps.org*. The web portal has both public and secure (restricted access) sections to ensure the security and privacy of selected interactions. As mentioned previously, requirements for survey vendors were previously finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79793 through 79794) and codified at § 419.46(h)(2). Hospitals will need to register on the OAS CAHPS Survey website (*https://oascahps.org*) in order to authorize the CMS-approved vendor to administer the survey and submit data on their behalf. Each hospital must then administer (via its vendor) the survey to all eligible patients (or for those anticipating more than 300 completed surveys, randomly sample their eligible patient population) treated during the data collection period on a monthly basis according to the

[414] Agency for Healthcare Research and Quality. ''The CAHPS Program.'' Available at: *https://ahrq.gov/cahps/index.html*.

guidelines in the Protocols and Guidelines Manual (*https://oascahps.org*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website.

Comment: A few commenters opposed the use of third-party survey vendors to administer OAS CAHPS data and stated the belief that many organizations have the capacity to build more secure, more patient-friendly, more community focused surveying platforms and questions, and that the financial expense of third-party vendors is not needed as evidenced by HCAHPS.

Response: In order to meet the survey administration requirements for these measures, the HOPD must administer the OAS CAHPS Survey in accordance with the requirements listed in the OAS CAHPS Survey Protocols and Guidelines Manual.[415]

OAS CAHPS Survey requires that the survey be administered by an approved survey vendor to ensure that patients respond to the survey in a way that reflects their actual experiences with outpatient surgical care and is not influenced by the facility. If vendors were removed as neutral third parties, there could be concerns of objectivity and bias.

We believe that OAS CAHPS Survey vendors have gained experience during the voluntary reporting as part of the voluntary National OAS CAHPS program, and approved vendors will be able to support HOPDs. We post the list of the approved OAS CAHPS vendors on *https://oascahps.org*, and we encourage HOPDs to contact vendors for cost and service information pertaining to OAS CAHPS as there may be differences among vendors and multiple modes of conducting the survey provide greater economical choice.

Comment: A commenter requested clarification on the ramifications if a HOPD does not receive enough completed surveys despite vendor attempts to collect information from eligible patients.

Response: We agree with commenters that patient response is largely out of the control of the facility. We clarify we did not propose to penalize HOPDs for patients' decision not to complete the survey. An HOPD will not receive a payment reduction as long as it participates in the survey, its vendor administers the survey according to the OAS CAHPS Survey Protocol and Guidelines Manual, and submits that data to CMS by the data submission deadline.

[415] *https://oascahps.org/Survey-Materials* Current Survey Materials (*oascahps.org*).

5. Data Submission Requirements for Measures Submitted via a Web-Based Tool for the CY 2023 Payment Determination and Subsequent Years

a. Data Submission Requirements for Measures Submitted via a CMS Web-Based Tool

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521), and the QualityNet website available at: *https://qualitynet.cms.gov* for a discussion of the requirements for measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2017 payment determination and subsequent years. We did not propose any changes to these policies in the proposed rule.

The following previously adopted quality measures require data to be submitted via a CMS web-based tool for the CY 2022 reporting period/CY 2024 payment determination and subsequent years:

- OP–22: Left Without Being Seen (NQF #0499); and
- OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658).

(1) Form, Manner, and Timing for Reporting OP–31: Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536)

In the CY 2022 OPPS/ASC Proposed rule (86 FR 42259) we proposed that this measure be submitted according to our existing policies for data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal). As noted earlier, we did not propose changes to those policies in the proposed rule.

We received no comments on this proposal regarding the form, manner, and timing for the OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure be submitted through the HQR System. As discussed in section XV.B.5.b. of this final rule with comment period, we are finalizing our proposal to require the reporting of the OP–31 measure with modification.

b. Data Submission Requirements for Measures Submitted via the CDC NHSN Website

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the previously finalized requirements for measure data submitted via the CDC NHSN website. While we did not propose any changes to those policies in the CY 2022 OPPS/ASC proposed rule (86 FR 42018), we did propose policies specific to the proposed COVID–19 Vaccination Coverage Among HCP measure (OP–38), which will be submitted via the CDC NHSN website.

(1) Form, Manner, and Timing for the COVID–19 Vaccination Coverage Among HCP Measure (OP–38) Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination and Subsequent Years

For the COVID–19 Vaccination Coverage Among HCP measure (OP–38), in the CY 2022 OPPS/ASC proposed rule (86 FR 86 FR 42260), we proposed to require reporting data on the number of HCP who have received the completed vaccination course of a COVID–19 vaccine by each individual facility's CCN.

For the COVID–19 Vaccination Coverage Among HCP measure (OP–38), we proposed that facilities would report COVID–19 vaccination data to the NHSN for at least one week each month, beginning with the January 1, 2022 through December 31, 2022 reporting period affecting the CY 2024 payment determination and continuing with quarterly reporting deadlines for subsequent years. If facilities report more than one week of data in a month, the most recent week's data would be used for measure calculation purposes. We proposed that hospitals would report the measure through the NHSN web-based surveillance system.[416] Specifically, hospitals would use the COVID–19 vaccination data reporting modules in the NHSN Healthcare Personnel Safety (HPS) Component to report the number of HCP eligible to have worked at the facility that week (denominator) and the number of those HCP who have received COVID–19 vaccination (numerator). Specific details on data submission for this measure can be found in the CDC's Overview of the Healthcare Safety Component, available at *https://www.cdc.gov/nhsn/PDFs/slides/NHSN-Overview-HPS_Aug2012.pdf*. We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75097 through 75100) for details about requirements for measure data submitted via the NHSN. In the CY 2022 OPPS/ASC proposed rule (86 FR 42260), we contemplated each quarter, the CDC would calculate a summary measure of

[416] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

COVID–19 vaccination coverage from the reporting periods for the quarter in four-quarter increments, when four quarters of data are available.

We refer readers to section XV.B.4.a.2. of this final rule with comment period received on the COVID–19 Vaccination Coverage Among HCP Measure (OP–38). We did not receive public comments on the form, manner, and timing for the COVID–19 Vaccination Coverage Among HCP Measure (OP–38); as such, we are finalizing our proposal to adopt the COVID–19 Vaccination Coverage Among HCP measure (OP–38) beginning with the CY 2022 reporting period/FY 2024 payment determination and subsequent years with the modifications described in section XV.B.4.a. of this final rule with comment period.

6. eCQM Reporting and Submission Requirements

a. Background

We believe that collection and reporting of data through health information technology would greatly simplify and streamline reporting for many CMS quality reporting programs. Through electronic reporting, hospitals will be able to leverage EHRs to capture, calculate, and electronically submit quality data to CMS for the Hospital OQR Program.

We believe that automated electronic extraction and reporting of clinical quality data would significantly reduce the administrative burden on hospitals for the Hospital OQR Program. We believe that the use of CEHRT can effectively and efficiently help providers improve internal care delivery practices, support management of patient care across the continuum, and support the reporting of eCQMs. In previous rules, we stated our intent and assessment of the inclusion of eCQMs into the Hospital OQR Program, and we have sought public comment on the addition of such measures into the measure set. We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75106 through 75107), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66956 through 66961), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70516 through 70518), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79785 through 79790), and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59435 through 59438) for more details on previous discussion regarding future measure concepts related to eCQMs and electronic reporting of data for the Hospital OQR Program, including stakeholder support for the introduction of eCQMs into the Program. Measure stewards and developers have worked to advance eCQMs that would be reported in the outpatient setting and we believe the introduction of eCQMs in the Hospital OQR Program is timely. We also believe this is important in aligning the Hospital OQR Program with the Medicare Promoting Interoperability Program and the Hospital IQR Program.

b. eCQM Reporting and Data Submission Requirements Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination

In section XV.B.4.c. of the CY 2022 OPPS/ASC proposed rule (86 FR 42244) and in section XV.B.4.c. of this final rule with comment period, we discuss adoption of the STEMI eCQM (OP–40). In the CY 2022 OPPS/ASC proposed rule (86 FR 42260), we proposed a progressive increase in the number of quarters for which hospitals report eCQM data. Increasing the number of reported quarters to be reported has several benefits. Primarily, a single quarter of data is not enough to capture trends in performance over time. Evaluating multiple quarters of data would provide a more reliable and accurate picture of overall performance. Further, reporting multiple quarters of data would provide hospitals with a more continuous information stream to monitor their levels of performance. Ongoing, timely data analysis can better identify a change in performance that may necessitate investigation and potentially corrective action.

However, we believe that starting with limited voluntary reporting would give hospitals more time to gain experience with reporting data (including time to implement the eCQM and provide training to support eCQM reporting, if necessary). Similar to what was established for the Hospital IQR Program (82 FR 38355), we believe that increasing the number of quarters for which hospitals report eCQM data would produce more comprehensive and reliable quality measure data for patients and providers. In section XV.B.4.c. of this final rule with comment period, we are finalizing the adoption of the STEMI eCQM (OP–40) with voluntary reporting beginning with the CY 2023 reporting period. For the CY 2023 reporting period, we proposed that hospitals submit STEMI eCQM (OP–40) data during this reporting period voluntarily for any quarter. Hospitals that chose to submit data voluntarily must submit in compliance with the eCQM certification requirements in sections XV.D.6.c., XV.D.6.d, and XV.D.6.e. of this final rule with comment period.

For the CY 2024 reporting period/CY 2026 payment determination, we proposed that hospitals report one self-selected calendar quarter of data for the STEMI eCQM (OP–40). We note that in section XV.B.4.c. of this final rule with comment period, we are finalizing that the STEMI eCQM (OP–40) is required beginning with the CY 2024 reporting period/CY 2026 payment determination.

For the CY 2025 reporting period/CY 2027 payment determination, we proposed to increase the amount of data required. We proposed that hospitals report two self-selected calendar quarters of data for the required STEMI eCQM (OP–40).

For the CY 2026 reporting period/CY 2028 payment determination, we proposed to further increase the amount of data required for the STEMI eCQM (OP–40). Specifically, we proposed to require that hospitals report three self-selected calendar quarters of data for the CY 2026 reporting period/CY 2028 payment determination for the required STEMI eCQM (OP–40). Beginning with the CY 2027 reporting period/CY 2029 payment determination, we proposed to require that hospitals report all four calendar quarters (one calendar year) of data for the required STEMI eCQM (OP–40).

We also refer readers to Table 68 for a summary of the finalized quarterly data increase in eCQM reporting beginning with the CY 2023 reporting period.

TABLE 68: Progressive Increase in eCQM Reporting Beginning with the CY 2023 Reporting Period/CY 2025 Payment Determination and for Subsequent Years

Calendar Year Period	Calendar Quarters of Reporting	Reporting
CY 2023 Reporting Period/CY 2025 Payment Determination	Any quarter(s)	Voluntary
CY 2024 Reporting Period/CY 2026 Payment Determination	One self-selected quarter	Mandatory
CY 2025 Reporting Period/CY 2027 Payment Determination	Two self-selected quarters	Mandatory
CY 2026 Reporting Period/CY 2028 Payment Determination	Three self-selected quarters	Mandatory
CY 2027 Reporting Period/CY 2029 Payment Determination and Subsequent Years	Four quarters (one calendar year)	Mandatory

We received comments on these topics.

Comment: One commenter suggested that we require hospitals submit one year of data instead of the incremental approach of increasing the number of quarters of data yearly.

Response: We thank the commenter for its feedback. We interpret the commenter's suggestion to mean that we should require hospitals to begin the initial data submission with one calendar year (four quarters) of eCQM data instead of the initial requirement to submit one quarter of data beginning with the CY 2024 reporting period/CY 2026 payment determination. While we appreciate the suggestion, we respectfully note that we proposed an incremental increase of data submission requirements to provide hospitals with a phased approach that would reduce reporting burden as eCQMs are new to the Hospital OQR Program.

We believe that hospitals should be given an opportunity to gain experience with reporting data (including time to implement the eCQM and provide training to support eCQM reporting, if necessary). Additionally, we aligned our approach with that of the Hospital IQR Program (82 FR 38355). In the FY 2018 IPPS/LTCH PPS final rule, we received public comment that resulted in the modification of the Hospital IQR Program's requirements to this incremental increase to alleviate stakeholder concerns and challenges with eCQM reporting (82 FR 38356). We believe it is important to learn from our approach and the public comments received regarding eCQMs in previous rulemaking for the Hospital IQR Program when proposing and finalizing equivalent requirements for the Hospital OQR Program. We believe our finalized policy to progressively increase the number of quarters of data collected over three years balances the benefit of additional eCQM data reported and allow adequate time for successful reporting experience. Any changes to eCQM reporting and submission requirements will be addressed in future notice and comment rulemaking.

Comment: One commenter recommended that we identify the time period of data submission instead of allowing hospitals to self-select which quarters of data to submit (prior to the requirement of one calendar year of data submission beginning with the CY 2027 reporting period/CY 2029 payment determination).

Response: We thank the commenter for the recommendation. We believe that allowing the flexibility to self-select quarter(s) of eCQM data to report, beginning with the CY 2024 reporting period/CY 2026 payment determination, will allow hospitals to gradually transition toward more robust electronic quality measure reporting. We believe that the ability to self-select quarters of data will provide the necessary time for quality, health IT, and clinical teams to gain experience and operationalize integration of eCQMs in the Hospital OQR Program. Additionally, we believe that smaller hospitals may require more time to become proficient in all the parameters (mapping, new workflows, education, etc.) associated with eCQM reporting. Therefore, we believe that following this same incremental approach for the Hospital OQR Program allows us to remain consistent across hospital quality reporting programs and reduce provider burden.

After consideration of the public comments we received, we are finalizing this proposal as proposed.

c. Electronic Quality Measure Certification Requirements for eCQM Reporting

(1) Requiring Use of 2015 Edition Cures Update Certified Technology Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination

In May 2020, the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) finalized updates to the 2015 Edition of health IT certification criteria (hereto referred to as the ''2015 Edition Cures Update''). These updates included revisions to the clinical quality measurement certification criterion at 45 CFR 170.315(c)(3) to refer to CMS Quality Reporting Data Architecture (QRDA) IGs and remove the Health Level 7 (HL7®) QRDA standard from the relevant health IT certification criteria (85 FR 25645). The ONC 21st Century Cures Act final rule provided health IT developers up to 24 months from May 1, 2020 to make technology certified to the updated and/or new criteria available to their customers (85 FR 25670). In November 2020, ONC issued an interim final rule with comment (85 FR 70064) which extended the compliance deadline for the update to the Clinical Quality Measures-Report criterion until December 31, 2022 (85 FR 70075). These updates were finalized to reduce burden on health IT developers under the ONC Health IT certification program (85 FR 25686) and have no impact on providers' existing reporting practices for CMS programs.

For the Hospital OQR Program, in the CY 2022 OPPS/ASC proposed rule (86 FR 42261), we proposed to require hospitals to utilize certified technology updated consistent with the 2015 Edition Cures Update for the CY 2023 reporting period/CY 2025 payment determination and subsequent years, which includes both the voluntary period and required submissions. We noted that this proposal is in alignment

with the Hospital IQR Program proposal in the FY 2022 IPPS/LTCH PPS proposed rule that requires use of technology updated consistent with 2015 Edition Cures Update beginning with the CY 2023 reporting period/FY 2025 payment determination (86 FR 25595), and which has since been finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45418).

We received no comments on this proposal. Therefore, we are finalizing this proposal as proposed.

d. File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

(1) File Format for EHR Data

Data can be collected in EHRs and health information technology systems using standardized formats to promote consistent representation and interpretation, as well as to allow for systems to compute data without needing human interpretation. As described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49701), these standards are referred to as content exchange standards because the standard details how data should be represented and the relationships between data elements. This allows the data to be exchanged across EHRs and health IT systems while retaining their meaning. Commonly used content exchange standards include the QRDA. The QRDA standard provides a document format and standard structure to electronically report quality measure data. We believe electronically reporting data elements formatted according to the QRDA standard would promote consistent representation and more efficient calculation of eCQM measure results.

Therefore, in alignment with the Hospital IQR Program file format requirements (85 FR 58940), in the CY 2022 OPPS/ASC proposed rule (86 FR 42262), we proposed that, beginning with the CY 2023 reporting period/CY 2025 payment determination, hospitals: (1) Must submit eCQM data via the QRDA Category I (QRDA I) file format; [417] (2) may use third parties to submit QRDA I files on their behalf; and (3) may either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I. Hospitals could meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemptions. We discuss the zero denominator declaration and case threshold exemptions in the subsequent sections. We also refer readers to section XV.B.8. of the CY 2022 OPPS/ASC proposed rule (86 FR 42256) and in this section of this final rule with comment period where we outline the maintenance of technical specifications including those for eCQMs.

Under this proposal, we expect QRDA I files to reflect data for one patient per file per quarter with five key elements necessary to identify the file:

- CMS Certification Number (CCN);
- CMS Program Name;
- EHR Patient ID;
- Reporting period specified in the Reporting Parameters Section; and
- EHR Submitter ID.

We received comments on these topics.

Comment: One commenter supported our alignment of these requirements with other quality reporting programs, particularly the Hospital IQR Program.

Response: We thank the commenter for their support.

After consideration of the public comments we received, we are finalizing this proposal as proposed.

(2) Zero Denominator Declarations

We understand there may be situations in which a hospital does not have data to report on a particular eCQM. Therefore, in the CY 2022 OPPS/ASC proposed rule (86 FR 42262), we proposed if the hospital's EHR is certified to an eCQM, but the hospital does not have patients that meet the denominator criteria of that eCQM, the hospital can submit a zero in the denominator for that eCQM. Submission of a zero in the denominator for an eCQM counts as a successful submission for that eCQM for the Hospital OQR Program. For example, if the hospital within the previously mentioned health system does not provide fibrinolytic therapy, but one of the eCQMs the health system's EHR is certified to is a fibrinolytic therapy measure, that hospital's EHR may render a zero in the denominator for that eCQM. The hospital will therefore report a zero denominator for that fibrinolytic therapy eCQM, and this will count toward the required eCQMs for the Hospital OQR Program. Hospitals within that health system for which that fibrinolytic therapy eCQM does apply will provide data on that measure.

We received one comment on these topics.

Comment: One commenter supported our alignment of these requirements with other quality reporting programs, particularly the Hospital IQR Program.

Response: We thank the commenter for its support.

After consideration of the public comments we received, we are finalizing this proposal as proposed.

(3) Case Threshold Exemptions

We understand that in some cases, a hospital may not meet the case threshold of discharges for a particular eCQM. In the CY 2022 OPPS/ASC proposed rule (86 FR 42262), we proposed to align with the case threshold exemption from the Medicare Promoting Interoperability Program (77 FR 54080) and the Hospital IQR Program (79 FR 50324). As stated for the Hospital IQR Program, the case threshold exemption means that for each quality measure for which hospitals do not have a minimum number of patients that meet the patient population denominator criteria for the relevant reporting period, hospitals would have the ability to declare a ''case threshold exemption'' if they have five or fewer applicable discharges. Specifically, for the Hospital OQR Program we propose that beginning with the CY 2023 reporting period/CY 2025 payment determination, if a hospital's EHR system is certified to report an eCQM and the hospital experiences 5 or fewer outpatient discharges per quarter or 20 or fewer outpatient discharges per year (Medicare and non-Medicare combined), as defined by an electronic clinical quality measure's denominator population, that hospital could be exempt from reporting on that electronic clinical quality measure. Case threshold exemptions are entered on the Denominator Declaration screen within the HQR System (formerly referred to as the QualityNet Secure Portal) available during the submission period.[418] The exemption would not have to be used; hospitals could report those individual cases if they would like to.

We received one comment on these topics.

Comment: One commenter supported our alignment of these requirements with other quality reporting programs, particularly the Hospital IQR Program.

Response: We thank the commenter for its support.

After consideration of the public comments we received, we are finalizing this proposal as proposed.

[417] QRDA I is an individual patient-level quality report that contains quality data for one patient for one or more eCQMs. QRDA creates a standard method to report quality measure results in a structured, consistent format and can be used to exchange eCQM data between systems. For further detail on QRDA I, the most recently available QRDA I specifications and Implementation Guides (IGs) can be found at: *https://ecqi.healthit.gov/qrda.*

[418] CMS Adds New Features to Denominator Declaration Screen for eCQM Reporting, available at: *https://qualitynet.cms.gov/news/5fa161829314190021d3c262.*

e. Submission Deadlines for eCQM Data

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), the Hospital IQR Program aligned their eCQM submission deadline with that of the Medicare Promoting Interoperability Program. The eCQM submission deadline for those two programs is the end of two months following the close of the CY (beginning with the CY 2017 reporting period/FY 2019 payment determination and for subsequent years).

In the CY 2022 OPPS/ASC proposed rule (86 FR 42262), for the Hospital OQR Program, we proposed to require eCQM data submission by the end of 2 months following the close of the calendar year for the CY 2023 reporting period/CY 2025 payment determination and for subsequent years. We believe that by aligning with the Hospital IQR and Promoting Interoperability Programs' deadlines, we would not add unnecessary burden. For example, for the CY 2023 reporting period/CY 2025 payment determination, hospitals that choose to voluntarily report that calendar year would be required to submit eCQM data by February 29, 2024, which is the end of 2 months following the close of the calendar year (December 31, 2023).

In developing this policy, we also considered proposing a submission deadline of May 15 to align with the submission deadline for Hospital OQR web-based measures. Under the Hospital OQR Program, the data submission period for web-based measures (for example, OP–29 and OP–31) extends through May 15 (we note the submission deadline may be moved to the next business day if it falls on a weekend or Federal holiday). However, we ultimately proposed instead to align eCQM data submission deadlines across quality reporting programs, because we believe that it would be less burdensome for hospitals.

We received comments on these topics.

Comment: One commenter supported our alignment of the submission deadline requirements across quality reporting programs.

Response: We thank the commenter for their support.

In the CY 2022 OPPS/ASC proposed rule (86 FR 42262), we indicated that we considered a deadline of May 15. To allow more time for data submission and for hospitals to review their data, we believe that a May 15 deadline is more appropriate. Additionally, this is consistent with the Hospital OQR Program data submission deadline for web-based measures which provides inter-program alignment. Therefore, after consideration of public comments, we are finalizing this proposal with modification, establishing May 15 as the data submission deadline for eCQMs for the CY 2023 reporting period/CY 2025 payment determination and for subsequent years. We note the submission deadline may be moved to the next business day if it falls on a weekend or Federal holiday.

7. Population and Sampling Data Requirements for the CY 2022 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our population and sampling requirements. We did not propose any changes to these policies in the proposed rule. We note that we did not propose any population and sampling data policies related to eCQM reporting, because we would expect data for all patients who meet the patient population denominator criteria to be reported.

8. Review and Corrections Period for Measure Data Submitted to the Hospital OQR Program

a. Chart-Abstracted Measures

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 and 67014) where we formalized a review and corrections period for chart-abstracted measures in the Hospital OQR Program. We did not propose any changes to these policies in the proposed rule.

b. Web-Based Measures

In the CY 2021 OPPS/ASC final rule (85 FR 86184), we finalized and codified to expand our review and corrections policy to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2023 payment determination and subsequent years. We did not propose any changes to these policies in the proposed rule.

c. Electronic Clinical Quality Measures (eCQMs)

In the CY 2022 OPPS/ASC proposed rule (86 FR 42263), we proposed that hospitals would have a review and corrections period for eCQM data submitted to the Hospital OQR Program. We proposed a review and corrections period for eCQM data which would run concurrently with the data submission period. The review and corrections period is from the time the submission period opens to the submission deadline. In the HQR System (formerly referred to as the QualityNet Secure Portal), providers can submit QRDA Category I test and production data files and can correct QRDA Category I test and production data files before production data is submitted for final reporting. We encourage early testing and the use of pre-submission testing tools to reduce errors and inaccurate data submissions in eCQM reporting. The HQR System does not allow data to be submitted or corrected after the annual deadline. We refer readers to the HQR System website (available at: *https://hqr.cms.gov/hqrng/login*) and the eCQI Resource Center (available at: *https://ecqi.healthit.gov/*) for more resources on eCQM reporting.

We received no comments on this proposal. Therefore, we are finalizing this proposal as proposed.

d. OAS CAHPS Measures

Each hospital administers (via its vendor) the survey for all eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (*https://oascahps.org*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website as stated in section XV.D.4.b.(2). of the CY 2022 OPPS/ASC proposed rule (86 FR 42259) and this final rule. As finalized in the CY 2017 OPPS/ASC final rule with comment period, data cannot be altered after the data submission deadline but can be reviewed prior to the submission deadline (81 FR 79793).

9. Hospital OQR Program Validation Requirements

a. Background

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105 through 72106), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), and 42 CFR 419.46(f) for our policies regarding validation.

b. Use of Electronic File Submissions for Chart-Abstracted Measure Medical Records Requests Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination and Subsequent Years

Currently, hospitals may choose to submit paper copies of medical records for chart-abstracted measure validation, or they may submit copies of medical

records for validation by securely transmitting electronic versions of medical information (79 FR 66965 through 66966). Submission of electronic versions can either entail downloading or copying the digital image of the medical record onto Compact Disc (CD), Digital Video Disc (DVD), or flash drive, or submission of Portable Document Format (PDF) using a secure file transmission process after logging into the HQR System (formerly referred to as the QualityNet Secure Portal) (79 FR 66966). We reimburse hospitals at $3.00 per chart (FY 2016 IPPS/LTCH PPS final rule (80 FR 49763)).

We strive to provide the public with accurate quality data while maintaining alignment with hospital recordkeeping practices. We appreciate that hospitals have rapidly adopted EHR systems as their primary source of information about patient care, which can facilitate the process of producing electronic copies of medical records. Additionally, we monitor the medical records submissions to the CMS Clinical Data Abstraction Center (CDAC) contractor and have found that almost two-thirds of hospitals already use the option to submit PDF copies of medical records as electronic files. In our assessment based on this monitoring, we believe requiring electronic file submissions can be a more effective and efficient process for hospitals selected for validation.

Therefore, in the CY 2022 OPPS/ASC proposed rule (86 FR 42263), we proposed to discontinue the option for hospitals to send paper copies of, or CDs, DVDs, or flash drives containing medical records for validation affecting the CY 2024 payment determination (that is, beginning with data submission for Q1 of CY 2022). We proposed to require hospitals to instead submit only electronic files when submitting copies of medical records for validation of chart-abstracted measures, beginning with validation affecting the CY 2024 payment determination (that is, Q1 of CY 2022) and for subsequent years. Under this proposal, hospitals would be required to submit PDF copies of medical records using direct electronic file submission via a CMS-approved secure file transmission process as directed by CDAC. We would continue to reimburse hospitals at $3.00 per chart, consistent with the current reimbursement amount for electronic submissions of charts. We note that this process would align with that for the Hospital IQR Program (FY 2016 IPPS/LTCH PPS final rule (85 FR 58949)).

Requiring electronic file submissions reduces the burden of not only coordinating numerous paper-based pages of medical records, but also of having to then ship the papers or physical digital media storage to the CDAC. Therefore, we believe it is appropriate to require that hospitals use electronic file submissions via a CMS-approved secure file transmission process.

We received comments on these topics.

Comment: Several commenters supported the proposed changes to require the use of electronic file submissions and remove the paper submission option beginning with the CY 2022 reporting period/CY2024 payment determination and for subsequent years because this change will align the data validation process for chart abstracted measures with the Hospital IQR Program.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing this proposal as proposed.

c. Time Period for Chart-Abstracted Measure Data Validation for Validations Affecting the CY 2024 Payment Determination and Subsequent Years

We refer readers to the chart-abstracted validation requirements and methods we adopted in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75117 through 75118) and codified at 42 CFR 419.46(f)(1) for the CY 2024 payment determination and subsequent years. In previous years, charts were requested by the CMS CDAC contractor and hospitals were given 45-calendar days from the date of the request to submit the requested records. If any record(s) were not received by the 45-day requirement, the CMS CDAC contractor assigned a ''zero'' validation score to each measure in a missing record. Using data from the CDAC, we have found that a large majority of hospitals that have participated in Hospital OQR Program data validation efforts have submitted their records prior to 30 calendar days in the current process. Furthermore, outpatient records typically contain significantly fewer pages than the inpatient records that hospitals have been submitting to the Hospital IQR Program for several years, which suggests that outpatient records could be gathered in less time and use less resources.

Therefore, in the CY 2022 OPPS/ASC proposed rule (86 FR 42263), we proposed to revise § 419.46(f)(1) to change the time period given to hospitals to submit medical records to the CDAC contractor from 45-calendar days to 30-calendar days, beginning with medical record submissions for encounters in Q1 of CY 2022/validations affecting the CY 2024 payment determination and for subsequent years. We proposed this deadline modification to reduce the time needed to complete validation, provide hospitals with feedback on their abstraction accuracy in a timelier manner, and to further align with the Hospital IQR Program's validation policy (76 FR 51645).

We received comments on these topics.

Comment: Several commenters supported this change to the time period given to hospitals to submit medical records to the CDAC contractor from 45-calendar days to 30-calendar days, beginning with medical record submissions for encounters in Q1 of CY 2022/validations affecting the CY 2024 payment determination and for subsequent years.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern with the proposal to reduce the submission time for validation from 45 to 30-calendar days. A few commenters noted that it takes time to review copied charts and recompile them for CDAC review. Commenters also noted that the time allotted for preparation of files will be even more important as measures move to eCQMs. A few other commenters mentioned that they do not support reducing hospital response times to validation requests without assurances from CMS that hospitals will receive timely feedback as a result. One commenter had concerns that given the scarce resources in health care currently, this proposal will present increased hardship to many facilities. The commenters requested that CMS continue to allow 45 days for submission of medical records to CDAC.

Response: As previously noted, the majority of participating hospitals in the Hospital OQR program have submitted their records prior to 30 calendar days in the current process according to the CDAC data. Given this, we believe that this adjusted timeline will not impose hardship on those hospitals. Additionally, our findings show that outpatient records contain less pages than inpatient records therefore, we do not anticipate that HOPDs will require additional time, resources, or administrative burden compared to inpatient hospitals, which already complete this process within the 30-day timeframe. We acknowledge that the reduction in time may require some hospitals to adjust their procedures to meet the new deadline, but this

proposal does not change the number of records requested, and we believe that a majority of hospitals have already shown the 30-day timeframe is feasible. Furthermore, as stated in the CY 2022 OPPS/ASC proposed rule (86 FR 42263 through 42264), this proposal would allow us to reduce the time needed to complete validation and provide hospitals with valuable and timely feedback of their results.

We also thank the commenters for their concern about the timing of this proposal as CMS shifts focus to eCQMs. As we gain more experience with eCQMs we will continue to monitor any potential challenges and adjust our validation requirements in future rulemaking if necessary.

After consideration of the public comments we received, we are finalizing this proposal as proposed.

d. Targeting Criteria

(1) Background

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), we finalized a validation selection process in which we select a random sample of 450 hospitals for validation purposes and select an additional 50 hospitals based on specific criteria. We finalized a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68485 through 68486), that for the CY 2014 payment determination and subsequent years, a hospital will be preliminarily selected for validation based on targeting criteria if it fails the validation requirement that applies to the previous year's payment determination. We also refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486 through 68487) for a discussion of finalized policies regarding our medical record validation procedure requirements. We codified at § 419.46(f)(3) that we select a random sample of 450 hospitals for validation purposes, and select an additional 50 hospitals for validation purposes based on the following criteria:

- The hospital fails the validation requirement that applies to the previous year's payment determination; or
- The hospital has an outlier value for a measure based on the data it submits. An ''outlier value'' is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals and indicates a poor score.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441), we clarified that an ''outlier value'' for purposes of this targeting is defined as a measure value that appears to deviate markedly from the measure values for other hospitals.

(2) Addition of Targeting Criteria

Beginning with validations affecting the CY 2022 reporting period/CY 2024 payment determination and subsequent years, in the CY 2022 OPPS/ASC proposed rule (86 FR 42264), we proposed to add to the two established targeting criteria used to select the 50 additional hospitals. Specifically, we proposed to revise § 419.46(f)(3) to add the following criteria for targeting the additional 50 hospitals:

- Any hospital that has not been randomly selected for validation in any of the previous 3 years.
- Any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent.

We stated in the proposed rule our belief that these proposals would allow more hospitals the opportunity for validation. First, by adding targeting criteria for any hospital that has not been randomly selected for validation in any of the previous 3 years, we can ensure that hospitals are eligible to be validated on a regular basis even if they are not selected under the randomly selected sample. Second, the option to selectively review hospitals that have a confidence interval that includes 75 percent is important because hospitals whose confidence interval includes 75 percent indicates a higher level of uncertainty as to the reliability of data for that particular hospital. By adding the targeting criteria for hospitals with two-tailed confidence interval that includes 75 percent, we can target those hospitals that are in the statistical margin of error for their accuracy (which includes hospitals that both pass and fail on this level). These proposals also align Hospital OQR Program validation with additional aspects of Hospital IQR Program validation (77 FR 53553). We believe that these proposed additional criteria would improve data quality by increased targeting of hospitals with possible or confirmed past data quality issues. Additionally, the proposal would respond to concerns that CMS does not have a methodology to address hospitals for which both passing and falling levels of accuracy were included for the statistical margin of error.[419]

We received comments on these topics.

Comment: A few commenters supported the proposed changes to the targeting criteria used in the data validation process beginning with the CY 2022 reporting period/CY 2024 payment determination and subsequent years.

Response: We thank the commenters for their support.

Comment: One commenter did not support targeting a hospital that passed validation in the previous year with a two-tailed confidence interval that includes 75 percent.

Response: We appreciate the commenters feedback and reiterate that validation continues to be an integral part of maintaining data integrity. We believe that finalizing these additional targeting criteria will provide more hospitals the opportunity to be selected for validation and ensure data integrity.

Comment: A few commenters provided recommendations to CMS regarding the targeting criteria for validation policies. One commenter urged CMS to coordinate validation requirements between the Hospital OQR and Hospital IQR programs to ensure that hospitals that are selected for validation are only required to validate data for the Hospital OQR or Hospital IQR program, instead of both programs. Another commenter noted that validation is an intense year long process for facilities and recommended that the administration should not repeatedly require administrative processes for validation efforts in order to create additional availability for important quality improvement initiatives.

Response: We appreciate the commenters' feedback and reiterate that validation is an important part of ensuring data integrity and that the finalization of these policies will help ensure data integrity and align validation policies across quality reporting programs. Each year there are only 10–15 hospitals that overlap in selection for validation. We closely review the selected hospitals to ensure there is no overlap in the record requests between the Hospital OQR and Hospital IQR programs. This review also allows us to ensure that hospitals have sufficient time to fulfill one request at a time. These policies are intended to align the Hospital OQR Program validation process with the Hospital IQR Program, which furthers overall cross-program alignment goals.

After consideration of the public comments we received, we are finalizing this proposal as proposed.

e. Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443) and

[419] Government Accountability Office. ''Hospital Quality Data. CMS needs more rigorous methods to ensure reliability of publicly released data''. GAO–06–54, January 2006.

the CY 2021 OPPS/ASC final rule with comment period (85 FR 86185), where we finalized and codified a policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction.

We did not propose any changes to these policies in the proposed rule.

10. Extraordinary Circumstances Exception (ECE) Process for the CY 2022 Payment Determination and Subsequent Years

a. Background

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59444), and 42 CFR 419.46(e) for a complete discussion of our extraordinary circumstances exception (ECE) process under the Hospital OQR Program.

b. Expanding the Extraordinary Circumstances Exemption to eCQMs

As part of our proposed policies in support of the introduction of eCQMs into the Hospital OQR Program, beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years, in the CY 2022 OPPS/ASC proposed rule (86 FR 42264), we proposed to expand our established Extraordinary Circumstances Exceptions policy to allow hospitals to request an exception from the Hospital OQR Program's eCQM reporting requirements based on hardships preventing hospitals from electronically reporting. We note that our proposal aligns with the Hospital IQR Program's Extraordinary Circumstances Exceptions policy for eCQMs (80 FR 49695, 42 CFR 412.140(c)(2)).

Under this proposal, applicable hardships could include, but are not limited to, infrastructure challenges (hospitals must demonstrate that they are in an area without sufficient internet access or face insurmountable barriers to obtaining infrastructure) or unforeseen circumstances, such as vendor issues outside of the hospital's control (including a vendor product losing certification). In addition, under the Hospital OQR Program, we may consider being a newly participating hospital as undergoing hardship such that newly participating hospitals can apply for an exemption for the applicable program year. Newly participating hospitals are required to begin data submission under the Hospital OQR Program procedural requirements at § 419.46(d)(1), which describes submission and validation of Hospital OQR Program data.

We also proposed that a hospital participating in the Hospital OQR Program that wishes to request an exception must submit its request to CMS by April 1 following the end of the reporting calendar year in which the extraordinary circumstances occurred. For example, if an extraordinary circumstance occurred on or by December 31, 2024, the ECE request must be submitted by April 1, 2025. Specific requirements for submission of a request for an exception would be available on the QualityNet website available at: *https://qualitynet.cms.gov/*. We received comments on these topics.

Comment: A few commenters expressed support for the expansion of the ECE policy to cover eCQMs under the Hospital OQR Program.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing this proposal as proposed.

11. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2022 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), the CY 2021 OPPS/ASC final rule with comment period (85 FR 68185), and 42 CFR 419.46(g) for our reconsideration and appeals procedures. We did not propose any changes to these policies in the proposed rule.

E. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2022 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to the proposed rule, which is available via the internet on the CMS website): ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''R'', ''S'', ''T'', ''V'', or ''U''. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79796), we clarified that the reporting ratio does not apply to codes with status indicator ''Q4'' because services and procedures coded with status indicator ''Q4'' are either packaged or paid through the Clinical Laboratory Fee Schedule and are never paid separately through the OPPS. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T''. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS

payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update and the reduced conversion factor uses the reduced OPD update. The baseline OPPS conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor − 0.02)

Reporting Ratio = Reduced Conversion Factor/Full Conversion Factor

Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor − 0.02)/(1 + OPD update factor)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: The wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, the rural sole community hospital adjustment, and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this final rule with comment period.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2022

We proposed to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2022 annual payment update factor. For the CY 2022 OPPS/ASC proposed rule, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of $84.457, equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $82.810. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. We proposed to continue to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''R'', ''S'', ''T'', ''V'', and ''U'' (other than new technology APCs to which we have proposed status indicator assignment of ''S'' and ''T''). We proposed to continue to exclude services paid under New Technology APCs. We proposed to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also proposed to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we proposed to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. In addition to our proposal to implement the policy through the use of a reporting ratio, we also proposed to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates.

For CY 2022, the proposed reporting ratio is 0.9805, which, when multiplied by the final full conversion factor of 84.457, equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of 82.810.

Comment: Two commenters asserted that the proposed reduced conversion factor of $82.810 and the proposed reporting ratio of 0.9805 are incorrect. Both commenters claim the proposed reduced conversion factor should be $83.227 and the proposed reporting ratio should be 0.9854. The commenters did not provide detailed calculations to support these assertions.

Response: We reviewed our calculations from the proposed rule after receiving these comments, and we were able to reconfirm our findings from the proposed rule that the reduced conversion factor was correctly calculated at $82.810 and the reporting ratio was correctly calculated at 0.9805. We would refer the commenters to the earlier text in this section (section XV.E.1. of this final rule with comment period) that provides a detailed description of the calculations we perform to generate the reduced conversion factor and the reporting ratio. In addition, we refer readers to the Conversion Factor calculation described in Part 2 of the OPPS Claims Accounting narrative, included with each proposed and final OPPS rule, available on the CMS website at: *https://www.cms.gov/*.

For this final rule with comment period, the final reporting ratio is 0.9804, which, when multiplied by the final full conversion factor of 84.177, equals a final conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of 82.526. We are finalizing our proposal to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. We are also finalizing our proposals to implement the policy through the use of a reporting ratio, and to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates for hospitals that fail to meet the Hospital OQR Program requirements for CY 2022 payment.

XVI. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIV.A.1. of this final rule with comment period (84 FR 61410) for a general overview of our quality reporting programs and to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58820 through 58822) where we previously discussed our Meaningful Measures Framework.

2. Statutory History of the ASCQR Program

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We refer readers to the CY 2014 through 2021 OPPS/ASC final rules with comment period for an overview of the regulatory history of the ASCQR Program:

- CY 2014 OPPS/ASC final rule (78 FR 75122);
- CY 2015 OPPS/ASC final rule (79 FR 66966 through 66987);
- CY 2016 OPPS/ASC final rule (80 FR 70526 through 70538);
- CY 2017 OPPS/ASC final rule (81 FR 79797 through 79826);
- CY 2018 OPPS/ASC final rule (82 FR 59445 through 59476);
- CY 2019 OPPS/ASC final rule (83 FR 59110 through 59139);
- CY 2020 OPPS/ASC final rule (84 FR 61420 through 61434); and
- CY 2021 OPPS/ASC final rule (85 FR 86187 through 86193).

We have codified requirements under the ASCQR Program at 42 CFR, part 16, subpart H (42 CFR 416.300 through 416.330).

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the priorities we consider for the ASCQR Program quality measure selection. We did not propose any changes to these policies in the proposed rule.

2. Retention and Removal of Quality Measures From the ASCQR Program

a. Retention of Previously Adopted ASCQR Program Measures

We previously finalized a policy that quality measures adopted for an ASCQR Program measure set for a previous payment determination year be retained in the ASCQR Program for measure sets for subsequent payment determination years, except when such measures are removed, suspended, or replaced as indicated (76 FR 74494 and 74504; 77 FR 68494 through 68495; 78 FR 75122; and 79 FR 66967 through 66969). We did not propose any changes to this policy in the proposed rule.

b. Removal Factors for ASCQR Program Measures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59111 through 59115), we clarified, finalized, and codified at § 416.320 an updated set of factors [420] and the process for removing measures from the ASCQR Program. We did not propose any changes to the measure removal factors in the proposed rule.

3. Proposal To Adopt a New Measure for the ASCQR Program Measure Set

In the CY 2022 OPPS/ASC proposed rule (86 FR 42267), we proposed to adopt one new measure: COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure (to be designated ASC–20) beginning with the CY 2022 reporting period/2024 payment determination.

a. Adoption of the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure (ASC–20) Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination

(1) Background

On January 31, 2020, the Secretary declared a public health emergency (PHE) for the United States (U.S.) in response to the global outbreak of SARS–CoV–2, a novel coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[421] COVID–19 is a contagious respiratory infection [422] that can cause serious illness and death. Older individuals, some racial and ethnic minorities, and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[423] [424] As of July 2, 2021, the U.S. reported over 33 million cases of COVID–19- and over 600,000 COVID–19 deaths.[425] As of October 14, 2021, the U.S. reported over 44 million cases and over 718,000

[420] We note that we previously referred to these factors as ''criteria'' (for example, 79 FR 66967 through 66969); we now use the term ''factors'' to align the ASCQR Program terminology with the terminology we use in other CMS quality reporting and pay-for-performance (value-based purchasing) programs.

[421] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*.

[422] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[423] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[424] Centers for Disease Control and Prevention. (2020). Health Equity Considerations and Racial and Ethnic Minority Groups. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html*.

[425] Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days*.

COVID–19 deaths.[426] Hospitals and health systems have seen significant surges of COVID–19 patients as community infection levels increased.[427] From December 2, 2020 through January 30, 2021, more than 100,000 Americans with COVID–19- were hospitalized at the same time.[428]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[429] Ongoing research indicates that fully vaccinated people without immunocompromising conditions are able to engage in most activities with very low risk of acquiring or transmitting SARS–CoV–2, and the Centers for Disease Control and Prevention (CDC) issued new guidance for fully vaccinated individuals on May 28, 2021.[430] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[431] Thus, the CDC advises that infections mainly occur through exposure to respiratory droplets when a person is in close contact with someone who has COVID–19.[432] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface [433] and that in certain circumstances, infection can occur through airborne transmission.[434] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed COVID–19 infection, regardless of whether the individual has symptoms.[435] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between HCP and patients or from patient to patient given the close contact that may occur during the provision of care.[436] The CDC has emphasized that health care settings can be high-risk places for COVID–19 exposure and transmission.[437]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[438] On December 11, 2020, the Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[439] Subsequently, FDA issued EUAs for additional COVID–19 vaccines.[440] [441] Following the publication of the proposed rule, FDA granted full approval to Comirnaty®, the Pfizer-BioNTech COVID–19 vaccine, on August 23, 2021.[442]

As part of its national strategy to address COVID–19, the White House stated on March 25, 2021 that it would work with states and the private sector to execute an aggressive vaccination strategy and outlined a goal of administering 200 million shots in 100 days.[443] On April 21, 2021, it was announced that this goal had been achieved.[444] Although the goal of the U.S. Government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, the Department of Health and Human Services, the Department of Defense, and the CDC, recommended that early vaccination efforts focus on those critical to the PHE response, including HCP, and individuals at highest risk for developing severe illness from COVID–19.[445] The CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccination, given the potential for transmission in health care settings and the need to preserve health care system capacity.[446] Reportedly most states followed this recommendation,[447] and HCP began

[426] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days*.

[427] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895*. Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html*.

[428] US Currently Hospitalized | The COVID Tracking Project. Accessed January 31, 2021 at: *https://covidtracking.com/data/charts/us-currently-hospitalized*.

[429] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[430] Centers for Disease Control and Prevention. (2021). Interim Public Health Recommendations for Fully Vaccinated People. Accessed on June 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html*.

[431] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[432] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[433] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[434] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[435] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html*.

[436] Centers for Disease Control and Prevention. (2021). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on April 2 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission*.

[437] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[438] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[439] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144412/download*.

[440] U.S. Food and Drug Administration. (2021). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download*.

[441] U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download*.

[442] U.S. Food and Drug Administration. (2021). Comirnaty and Pfizer-BioNTech COVID–19 Vaccine. Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine*

[443] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on April 3, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/*.

[444] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on June 2, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/21/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations-2/*.

[445] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf;* Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[446] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[447] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/*.

receiving the vaccine in mid-December of 2020.[448]

Frontline healthcare workers, such as those employed in ASCs, have been prioritized for vaccination in most locations. There are approximately 18 million healthcare workers in the U.S.[449] A survey of HCP found that 66 percent of hospital HCP and 64 percent of outpatient clinic HCP reported receiving at least one dose of the vaccine.[450] As of July 2, 2021, the CDC reported that over 328 million doses of COVID–19 vaccine have been administered and approximately 155.9 million people had received full doses.[451] Subsequently, the CDC reported that as of October 14, 2021, over 405 million doses of COVID–19 vaccine have been administered and approximately 188.3 million people had received full doses.[452] The White House indicated on April 6, 2021 that the U.S. retains sufficient vaccine supply, and every adult became eligible to receive the vaccine beginning April 19, 2021.[453] Finally, as part of the efforts to vaccinate those who are still unvaccinated through increasing the number of Americans covered by vaccination requirements,[454] on September 9, 2021, the Biden Administration announced that COVID–19 vaccination will be required of all staff within Medicare and Medicaid-certified facilities to protect both patients and HCP against COVID–19.[455]

We believe it is important to require that ASCs report HCP vaccination information for health care facilities to assess whether these facilities are taking this step to limit the spread of COVID–19 among their health care workers and to help sustain the ability of ASCs to continue serving their communities throughout the PHE and beyond. Therefore, we proposed adoption of a new measure, COVID–19 Vaccination Coverage Among HCP (ASC–20), beginning with the CY 2024 payment determination. For that payment year, ASCs would be required to report data quarterly on the measure for the January 2022 through December 2022 reporting period. The measure would assess the proportion of an ASC's health care workforce that has been vaccinated against COVID–19.

HCP are at risk of transmitting COVID–19 infection to patients, experiencing illness or death as a result of COVID–19 infection themselves, and transmitting it to their families, friends, and the general public. We believe ASCs should report the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. HCP vaccination can reduce illness that leads to work absence and limit disruptions to providing care[456] with major reductions in SARS–CoV–2 infections among those receiving a two dose COVID–19 vaccine despite a high community infection rate.[457] Data from influenza vaccination demonstrate that provider vaccination is associated with that provider recommending vaccination to patients[458] and we believe HCP COVID–19 vaccination in ASCs could similarly increase vaccination among that patient population. We also believe that publishing the HCP vaccination rates will be helpful to many patients, particularly those who are at high-risk for developing serious complications from COVID–19, as they choose among ASCs for treatment. Under CMS' Meaningful Measures Framework, the COVID–19 measure addresses the quality priority of ''Promote Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

(2) Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure (''COVID–19 HCP vaccination measure'') (ASC–20) is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in non-LTC facilities including ASCs.

(a) Measure Specifications

The denominator for the HCP measure is the number of HCP eligible to work in the ASC for at least 1 day during the reporting period, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[459]

The numerator for the HCP measure is the cumulative number of HCP eligible to work in at the ASC for at least 1 day during the reporting period and who received a complete vaccination course against COVID–19.[460] [461] [462] [463] A complete vaccination course may require multiple doses or regular revaccination.[464] Vaccination coverage for purposes of this measure is defined

[448] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f.*

[449] Centers for Disease Control and Prevention. Healthcare Workers. (2017) Accessed February 18, 2021 at: *https://www.cdc.gov/niosh/topics/healthcare/default.html.*

[450] KFF/The Washington Post Frontline Health Care Workers Survey. (2021). Accessed June 2, 2021 at: *https://www.kff.org/coronavirus-covid-19/poll-finding/kff-washington-post-health-care-workers/.*

[451] Centers for Disease Control and Prevention. (2021), COVID Data Tracker. COVID–19 Vaccinations in the United States. Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations.*

[452] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. (2021). COVID Data Tracker. COVID–19 Vaccinations in the United States. Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations.*

[453] The White House. Remarks by President Biden Marking the 150 Millionth COVID–19 Vaccine Shot. Accessed April 8, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/06/remarks-by-president-biden-marking-the-150-millionth-covid-19-vaccine-shot/.*

[454] The White House. Path Out of the Pandemic: President Biden's COVID–19 Action Plan. Accessed on October 14, 2021. Available at: *https://www.whitehouse.gov/covidplan/#vaccinate.*

[455] CMS. Press Release: Biden-Harris Administration to Expand Vaccination Requirements for Health Care Settings. September 9, 2021. Available at: *https://www.cms.gov/newsroom/press-releases/biden-harris-administration-expand-vaccination-requirements-health-care-settings.* In order to implement this plan, CMS is working with the CDC to develop an Interim Final Rule with Comment Period that will extend emergency regulations to require vaccination among staff in a wide range of healthcare settings including dialysis facilities. This action will create a consistent standard across the country, while giving patients assurance of the vaccination status of those delivering care.

[456] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm.*

[457] Benenson S, Oster Y, Cohen MJ, Nir-Paz R. BNT162b2 mRNA Covid-19 Vaccine Effectiveness among Health Care Workers. N Engl J Med. 2021. See also: Keehner J, Horton LE, Pfeffer MA, Longhurst CA, Schooley RT, Currier JS, et al. SARS–CoV–2 Infection after Vaccination in Health Care Workers in California. N Engl J Med. 2021.

[458] Measure Application Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[459] Centers for Disease Control and Prevention. Contraindications and precautions. (2021) Accessed March 15, 2021 at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications.*

[460] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[461] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage Updated August 2021. Available at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.*

[462] National Health Safety Network. Healthcare Personnel COVID–19 Vaccination Cumulative Summary (CDC 57.219, Rev 5). Updated September 2021. Available at: *https://www.cdc.gov/nhsn/forms/57.219-p.pdf.*

[463] Centers for Disease Control and Prevention. Frequently Asked Questions about COVID–19 Vaccination. How do I know if I have been fully vaccinated if I was vaccinated in another country? *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html* (updated October 21, 2021).

[464] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

as the estimated percentage (given the potential for week-to-week variation) of HCP eligible to work at the ASC for at least 1 day who received a COVID–19 vaccine. For reporting, facilities would count HCP working in all facilities that share the same CMS certification number (CCN).[465] The specifications for the COVID–19 HCP vaccination measure (ASC–20) are available on the NQF website at: *https://www.cdc.gov/nhsn/nqf/index.html*.[466]

(b) Review by the Measure Applications Partnership

The COVID–19 HCP vaccination measure (ASC–20) was included on the publicly available ''List of Measures Under Consideration for December 21, 2020,'' [467] a list of measures under consideration for use in various Medicare programs. The Measure Applications Partnership (MAP) hospital workgroup convened on January 11, 2021 and reviewed the Measures Under Consideration (MUC) List including the COVID–19 HCP vaccination measure (ASC–20). The MAP hospital workgroup agreed that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it could bring value to the ASCQR Program measure set by providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[468] The MAP hospital workgroup also stated in its recommendations that collecting information on COVID–19 vaccination coverage among HCP and providing feedback to facilities will allow facilities to benchmark coverage rates and improve coverage in their facility, and that reducing COVID–19 infection rates in HCP may reduce transmission among patients and reduce instances of staff shortages due to illness.[469]

In its preliminary recommendations, the MAP hospital workgroup did not support this measure for rulemaking, subject to potential for mitigation.[470] To mitigate its concerns, the MAP hospital workgroup believed that the measure needed well-documented evidence, finalized specifications, testing, and National Quality Forum (NQF) endorsement prior to implementation.[471] Subsequently, the MAP Coordinating Committee met on January 25, 2021 and reviewed the COVID–19 HCP vaccination measure (ASC–20). In the 2020 and 2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measures back to MAP once the specifications are further refined.[472] The MAP stated, ''the incomplete specifications require immediate mitigation and further development should continue.'' [473] In its final report, the MAP noted that the measure would add value by providing visibility into an important intervention to limit COVID–19 infections in HCP and the patients for whom they provide care.[474] The spreadsheet of final recommendations no longer cited concerns regarding evidence, testing, or NQF endorsement.[475] In response to the MAP final recommendation request that CMS bring the measure back to the MAP once the specifications are further refined, CMS and the CDC met with the MAP Coordinating Committee on March 15, 2021. CMS and CDC provided additional information to address vaccine availability, alignment of the COVID–19 HCP vaccination measure (ASC–20) as being as closely as possible with the data collection for the Influenza HCP vaccination measure (NQF #0431), and provided clarification on how HCP are defined. CMS and the CDC also presented preliminary findings from the testing of the numerator of the COVID–19 HCP vaccination measure, which is currently in process. These preliminary findings show numerator data should be feasible to collect and reliable. Testing of the measure numerator (the number of HCP vaccinated) involves a comparison of the data collected through the National Healthcare Safety Network (NHSN) and independently reported through the Federal pharmacy partnership program for delivering vaccination to LTC facilities. These are two independent data collection systems. In initial analyses of the first month of vaccination, the number of healthcare workers vaccinated in approximately 1,200 facilities for which data from both systems were available, the number of healthcare personnel vaccinated was highly correlated between the two systems with a correlation coefficient of nearly 90 percent in the second 2 weeks of reporting.[476] Because of the high correlation across a large number of facilities and high number of HCP within those facilities receiving at least one dose of the COVID–19 vaccine, we believe the measure is feasible and reliable for use in ASCs. After reviewing this additional information, the MAP retained its final recommendation of conditional support, and expressed support for CMS' efforts to use the measure as part of the solution for the COVID–19 public health crisis.[477]

Section 1890A(a)(4) of the Act, as added by section 3014(b) of the Affordable Care Act, requires the Secretary to take into consideration input from multi-stakeholder groups in selecting certain quality and efficiency measures. While we value input from the MAP, we believe it is important to propose the measure as quickly as possible to address the urgency of the COVID–19 PHE and its impact on vulnerable populations. CMS continues to engage with the MAP to mitigate concerns and appreciates the MAP's conditional support for the measure.

(c) Measure Endorsement

Section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act shall apply with respect to ASC services in a similar manner in which it applies to hospitals for the Hospital OQR Program, except as the Secretary may otherwise provide. The requirements at section 1833(t)(17)(C)(i) of the Act state that measures developed shall ''be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.''

In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to

[465] Centers for Disease Control and Prevention. CMS Reporting Requirements FAQs. Accessed June 2, 2021 at: *https://www.cdc.gov/nhsn/PDFs/CMS/faq/FAQs-CMS-Reporting-Requirements.pdf*.

[466] *https://www.cdc.gov/nhsn/nqf/index.html*.

[467] *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212*.

[468] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

[469] *Ibid.*

[470] *Ibid.*

[471] *Ibid.*

[472] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 3, 2021 at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*.

[473] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

[474] *Ibid.*

[475] *Ibid.*

[476] For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[477] *Ibid.*

consensus development. However, as we have noted in previous rulemaking (for example, 75 FR 72065 and 76 FR 74494 for the Hospital OQR and ASCQR Programs, respectively), the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

The COVID–19 HCP vaccination measure (ASC–20) is not NQF-endorsed and has not been submitted to NQF for endorsement consideration. The CDC, in collaboration with CMS, is planning to submit the measure for consideration in the NQF Fall 2021 measure cycle. However, we found no other feasible and practicable measures on the topic of COVID–19 vaccination among HCP.

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 practicable measure has not been endorsed by the entity with a contract under section 1890(a) (currently the NQF), 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. Therefore, with the above considerations, we believe there is sufficient basis to propose the adoption of this measure at this time.

(d) Data Collection, Submission, and Reporting

Given the time sensitive nature of this measure considering the current PHE, we proposed that ASCs would be required to begin reporting data on the COVID–19 HCP vaccination measure (ASC–20) beginning January 1, 2022, for the CY 2024 payment determination for the ASCQR Program. Thereafter, we proposed quarterly reporting periods. While we considered annual reporting periods for the ASCQR Program, we proposed quarterly reporting periods given the immediacy of the PHE and the importance of alignment across quality payment programs that proposed this measure.

In the CY 2022 OPPS/ASC proposed rule (86 FR 42270), we stated that ASCs would report the measure through the CDC NHSN web-based surveillance system.[478] While the ASCQR Program does not currently require use of the NHSN web-based surveillance system, we previously required use of this system for submitting program data. We refer readers to the CY 2014 OPPS/ASC final rule with comment period in which we adopted the Influenza Vaccination Coverage Among HCP (NQF #0431) measure (78 FR 75110 through 75117) and section XVI.D.1.c.(2). of the CY 2022 OPPS/ASC proposed rule (86 FR 42282) for additional information on reporting through the NHSN web-based surveillance system under the ASCQR Program. The Influenza Vaccination Coverage Among HCP (NQF #0431) measure was removed from the ASCQR Program in the CY 2019 OPPS/ASC final rule with comment period as CMS observed that reporting measure data through the NHSN could be more burdensome for ASCs compared to the relative burden for hospitals participating in the Hospital IQR Program and the HAC Reduction Program and especially for freestanding ASCs (83 FR 59115 through 59117). However, the COVID–19 pandemic and associated PHE have had a more significant effect on more aspects of society than influenza, including availability of the healthcare system. With respect to reporting for the COVID–19 HCP vaccination measure (ASC–20), CDC guidance for entering data requires submission of HCP count at the facility level[479] and the measure requires reporting consistent with that guidance. We believe that the public health benefits to having these data available outweigh the burden of reporting for systems with multiple facilities or locations. While we recognize that there may be some elements of the measure specifications that increase burden for some ASCs, given the impact that the COVID–19 PHE has had on society and the healthcare system, we believe that the benefits outweigh this reporting burden. For more information on the associated burden of this measure, we refer readers to XXV.C.5.b. of the CY 2022 OPPS/ASC proposed rule.

To report this measure, we proposed that ASCs would collect the numerator and denominator for the COVID–19 HCP vaccination measure (ASC–20) for at least one, self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet ASCQR Program requirements. While we believe that it would be ideal to have HCP vaccination data for every week of each month, we are mindful of the time and resources that ASCs would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least 1 week of each month would be sufficient to obtain a reliable estimate of vaccination levels among an ASC's HCP while balancing the costs of reporting. If an ASC submits more than 1 week of data in a month, the most recent week's data would be used to calculate the measure. For example, if first and third week data are submitted, third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. Each quarter, we proposed that the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each ASC, which would be calculated by taking the average of the data from the three submission periods submitted by the ASC for that quarter. CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

ASCs would submit the number of HCP eligible to have worked at the facility during the self-selected week that the ASC reports data in NHSN (denominator) and the number of those HCP who have received a complete course of a COVID–19 vaccination (numerator) during the same self-selected week. As previously stated, facilities would count HCP working in all facilities that share the same CCN.[480]

We received comments on these topics. We note that this measure was also proposed for the Hospital Outpatient Quality Reporting Program; comments specific to hospitals and this program are discussed in section XV.B.4.a. of this final rule with comment period.

Comment: Many commenters supported our proposal to adopt the COVID–19 Vaccination Coverage Among HCP measure (ASC–20) and expressed the importance of vaccination in the fight against COVID–19. Some commenters stated that reporting the measure will ensure transparency and accountability in infection prevention and control for vulnerable populations and communities. Other commenters appreciated that the measure would make COVID–19 vaccination information available to the public in health care decisions.

Response: We thank commenters for their support of the measure and agree that the measure is critically important in the ongoing fight against COVID–19. Additionally, we agree with the commenter that reporting and

[478] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

[479] Centers for Disease Control and Prevention. COVID–19 Vaccination Non-LTC Healthcare Personnel TOI *https://www.cdc.gov/nhsn/index.html.*

[480] *Ibid.*

publication of this measure would assist the public in making more informed health care decisions.

Comment: A few commenters expressed concern that COVID–19 vaccines are authorized under EUA, and the measure should not be adopted until such time that a vaccine has received full FDA approval. One commenter observed that all three currently available vaccines should be fully approved by FDA prior to adoption of this measure to reduce vaccine hesitancy.

Response: On August 23, 2021, subsequent to the publication of the CY 2022 OPPS/ASC proposed rule (86 FR 42267), FDA granted full approval to Comirnaty®, which has been known as the Pfizer-BioNTech COVID–19 vaccine.[481] While we recognize there are differences between EUA authorization and full FDA approval, we note that the process for each is scientifically rigorous and we refer readers to information related to FDA's process for evaluating an Emergency Use Authorization (EUA) request at *https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization vaccines-explained*. Each vaccine manufacturer that received EUA authorization enrolled tens of thousands of participants in randomized clinical trials, which is similar to what is required for full FDA approval.[482] Manufacturers submit robust and rigorous data for both an EUA authorization and full FDA approval, and more than 404 million doses of COVID–19 vaccines have been administered.[483] We believe all COVID–19 vaccines granted full approval and EUA authorization to be proven safe and effective and we believe it is appropriate to include the measure in the ASCQR Program.

We further note that the COVID–19 Vaccination Coverage Among HCP measure does not itself require HCP to receive the vaccination, nor does this measure reward or penalize HOPDs for the rate of HCP who have received a COVID–19 vaccine. The COVID–19 Vaccination Coverage Among HCP measure requires HOPDs to collect and report COVID–19 vaccination data that would support public health tracking and provide beneficiaries and their caregivers information to support informed decision making.

Comment: Several commenters opposed adoption of the COVID–19 Vaccination Coverage Among HCP measure (ASC–20) due to a lack of evidence that ASCs contribute to the spread of COVID–19. These commenters cited a survey that found that, despite ASCs performing essential outpatient surgeries during March and April 2020, patients faced virtually no increase to the risk of contracting COVID–19.[484]

Response: We appreciate the commenters' feedback. Patient safety is a top priority of the ASCQR Program, and we believe that the COVID–19 Vaccination Coverage Among HCP measure (ASC–20) will promote infection prevention and control for patients as well as HCP and other staff working in ASCs. We acknowledge that there is evidence that ASCs previously experienced low rates of COVID–19 among patients. The survey cited by the commenter and conducted by the ASC Quality Collaboration surveyed 709 ASCs in eight states about outpatient surgical procedures performed on 84,446 patients in March and April 2020; only 16 patients tested positive for COVID–19 within 14 days after the procedure.[485] We note that incidence of new cases and the nation's capacity to test for new cases during the March and April 2020 time frame cited in the survey shared by the commenters is not representative of current conditions. At the time, new cases per day did not exceed 35,000. More recently, COVID–19 cases and deaths nationally have continued to rise. Comparatively in recent months, new cases per day have reached more than 189,000 with seven-day average case rates exceeding 100,000 during most of August and September 2021.[486] Since the publication of the proposed rule, the emergence of coronavirus variants have resulted in 8.9 million new virus cases.[487] Thus, we believe it is appropriate to adopt the COVID–19 Vaccination Coverage Among HCP measure in the ASCQR Program as soon as possible to further infection control efforts and to increase transparency regarding vaccination status of HCP.

Comment: Some commenters stated that it is inappropriate to use payment policies to drive vaccination coverage among HCP. Some commenters expressed concern that this measure could lead facilities to mandate vaccines for staff, with potential unintended consequences (specifically, staff quitting or legal risk for facilities for staff experiencing adverse events).

Response: We note that this measure does not financially reward or punish ASCs for their vaccine coverage rate. As part of the ASCQR Program, an ASC's payment is affected only if it fails to report the requisite measures, not by the rate it reports. As such, we do not believe that the adoption of this measure uses Medicare payment policies to drive vaccination coverage among HCP. Additionally, we believe that publicly reporting the data will be useful to consumers in choosing healthcare providers, including by making comparisons between ASCs. We noted in the CY 2022 OPPS/ASC proposed rule (86 FR 42239), a survey of HCP from April 2021 found that 66 percent of hospital HCP and 64 percent of outpatient clinic HCP reported receiving at least one dose of the vaccine.[488] Subsequent to the publication of the CY 2022 OPPS/ASC proposed rule, research from August 2021 suggests that nearly 73 percent of HCP across all health care facilities have received at least one dose of the vaccine.[489] Based on these findings, we understand that HCP have been receiving the COVID–19 vaccine prior to the adoption and we believe that this measure encourages continued vaccination within ASCs.

[481] U.S. Food and Drug Administration. Comirnaty and Pfizer-BioNTech COVID–19 Vaccine. August 30, 2021. Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine*.

[482] Harvard Law Petrie-Flom Center. ''What's the Difference Between Vaccine Approval (BLA) and Authorization (EUA)?'' June 15, 2021. Available at: *https://blog.petrieflom.law.harvard.edu/2021/06/15/whats-the-difference-between-vaccine-approval-bla-and-authorization-eua/*.

[483] Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker: COVID–19 Vaccinations in the United States. Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations*.

[484] Mukerji, S. ASC QC COVID–19 Survey Confirms Continued safety in ASCs. ASC Focus. December 2020. Available at: *https://www.ascfocus.org/ascfocus/content/articles-content/articles/2020/digital-debut/asc-qc-covid-19-survey-confirms-continued-safety-in-ascs*.

[485] Mukerji, S. ASC QC COVID–19 Survey Confirms Continued safety in ASCs. ASC Focus. December 2020. Available at: *https://www.ascfocus.org/ascfocus/content/articles-content/articles/2020/digital-debut/asc-qc-covid-19-survey-confirms-continued-safety-in-ascs*.

[486] Centers for Disease Control and Prevention. Trends in Number of COVID–19 Cases and Deaths in the U.S. Reported to CDC for March 1–April 30, 2020 and August 1–September 20, 2021. Available at: *https://covid.cdc.gov/covid-data-tracker/#trends_dailycases*.

[487] Centers for Disease Control and Prevention. Trends in Number of COVID–19 Cases and Deaths in the U.S. Reported to CDC. Accessed September 22, 2021. Available at: *https://covid.cdc.gov/covid-data-tracker/#trends_totalcases*.

[488] KFF/The Washington Post Frontline Health Care Workers Survey. (2021). Available at: *https://www.kff.org/coronavirus-covid-19/pollfinding/kff-washington-post-health-care-workers/*.

[489] Lazer, D. et al. THE COVID STATES PROJECT: A 50-STATE COVID–19 SURVEY REPORT #62: COVID–19 VACCINE ATTITUDES AMONG HEALTHCARE WORKERS. Northeastern University, Harvard University, Rutgers University, and Northwestern University. August 16, 2021. Available at: *http://news.northeastern.edu/uploads/COVID19%20CONSORTIUM%20REPORT%2062%20HCW%20August%202021.pdf*.

Comment: One commenter requested clarification on the definition of ''health care personnel.'' Several commenters expressed a preference for data collection at the NPI level instead of by CCN.

Response: We recognize commenters' concerns regarding the reporting burden associated with the specifications of this measure, specifically around the definition of HCP. We note that given the highly infectious nature of the COVID–19 virus, we believe it is important to encourage all personnel within the hospital, regardless of patient contact, role, or employment type, to receive the COVID–19 vaccination to prevent outbreaks within the hospital which may affect resource availability and have a negative impact on patient access to care. We also note that the measure specifications define ''eligible'' HCP as all persons receiving a direct paycheck from the reporting facility (that is, on the facility's payroll), regardless of clinical responsibility or patient contact, licensed independent practitioners, and adult students/trainees and volunteers.[490] We recognize that ASCs utilize their NPIs for billing and are more familiar with this identifier; whereas, the NHSN system has been constructed to use the CCN as the facility identifier. A look-up tool mapping NPI to CCN is available for ASCs at *https://www.qualityreportingcenter.com/en/ascqr-program/data-dashboard/ccn/*.

Comment: Several commenters expressed concern that this measure should not be adopted until there is clarity around the impact of future booster recommendations. One commenter stated that the numerator requirement of a completed vaccination course may change over time and recommended that CMS establish a definition of completed vaccination course using the national guidelines as of the date the OPPS final rule is published each year. Other commenters recommended that reporting for the measure should be optional or delayed until a completed vaccination course can be more clearly and specifically defined.

Response: The COVID–19 Vaccination Coverage Among HCP measure (ASC–20) is a measure of a completed vaccination course (as defined in section XVI.B.3.a.2. of the CY 2022 OPPS/ASC proposed rule (86 FR 42268)) and does not address booster shots. On August 12, 2021, FDA amended the EUAs for both the Pfizer-BioNTech COVID–19 Vaccine and the Moderna COVID–19 Vaccine to allow for the use of an additional dose in certain immunocompromised individuals, specifically, solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.[491] The Centers for Disease Control on September 27, 2021 further recommended Pfizer-BioNTech boosters for individuals who completed their initial series at least six months ago and are 65 years of age or older; 18 years of age or older with underlying medical conditions; and 18 years of age or older living and working in high-risk settings, which includes healthcare workers.[492] We acknowledge commenter concerns that ASCs will be required to collect additional information from HCP on booster doses. However, we believe that the numerator is sufficiently broad to include future boosters as part of a ''complete vaccination course.''

Comment: Several commenters cited Equal Employment Opportunity Commission (EEOC) guidelines, which state that employers must provide a reasonable accommodation if an employee's sincerely held religious belief, practice, or observance prevents them from receiving the vaccination. The commenters requested that CMS and the CDC revise the measure exclusions to align with EEOC guidance. One commenter expressed concern that the measure may lead to violation of individual employee's rights to choose whether to receive the vaccine.

Response: We recognize that there are reasons, including religious objections or concerns regarding an individual's specific health status, that may lead individual HCP to decline vaccination. We emphasize that this measure does not mandate vaccines, it only requires reporting of vaccination rates for successful program participation. However, we believe that accurate vaccination rates of HCP are meaningful data for patients and beneficiaries to use when choosing an ASC. The CDC, the measure's steward, offers guidance regarding the reporting on HCP who decline vaccination due to religious reasons. Those HCP, however, would be included in the measure denominator along with other HCP who have not received a completed vaccination course.[493]

We further note that the EEOC released updated and expanded technical assistance on May 28, 2021, stating that Federal equal employment opportunity (EEO) laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID–19, so long as the employer complies with the reasonable accommodation provisions of the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 and other EEOC considerations.[494] Thus, we do not believe that this measure conflicts with any EEOC guidance and believe it is appropriate to require facilities to report these data.

Comment: A few commenters noted that, while vaccination plays an important role in ending the COVID–19 pandemic, the measure is not currently endorsed by the National Quality Forum and these commenters believed it should not be adopted until it receives such an endorsement. One commenter observed that NQF endorsement improves credibility and affords patients certainty that the measure data is reliable. One commenter recommended that CMS clarify that the adoption of a measure prior to NQF endorsement is only due to the exigency of the current circumstances. One commenter expressed a preference for measures that have been thoroughly tested and reviewed.

Response: We acknowledge that the COVID vaccination of HCP measure is not NQF endorsed. However, as discussed in section XVI.B.3.a.(2).(c). of this final rule with comment period and below, we believe it is appropriate to develop and select this measure and that such development and selection is consistent with section 1833(i)(7)(B) of the Act. While we prefer to develop measures endorsed by a consensus building entity such as the NQF, we note that sections 1833(i)(7)(B) and 1833(t)(17)(C) of the Act do not limit CMS to developing and selecting such measures.

[490] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage Updated August 2021. Available at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf*.

[491] U.S. Food and Drug Administration. Coronavirus (COVID–19) Update: FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals. August 12, 2021. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised*.

[492] *Ibid.*

[493] Centers for Disease Control and Prevention. Reporting Weekly COVID–19 Vaccination Data for Healthcare Personnel Using the National Healthcare Safety Network (NHSN). September 2021. Available at: *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/weekly-covid-reporting-508.pdf*.

[494] U.S. Equal Employment Opportunity Commission. What You Should Know About COVID–19 and the ADA, the Rehabilitation Act, and Other EEO Laws. May 28, 2021. Available at: *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws*.

At this time, there is no NQF endorsed measure addressing the COVID–19 vaccination rate of HCP. Further, we believe that in the context of the current COVID–19 PHE and continued monitoring and surveillance following the PHE, it is important to adopt this measure as quickly as possible to allow tracking and reporting of COVID–19 Vaccination Coverage Among HCP. This tracking would allow facilities to identify the appropriateness and effectiveness of their infection control efforts, their initiatives to improve vaccination coverage, and would provide patients and consumers with important information for them to make more informed health care decisions. As such, it is neither feasible nor practical for CMS to delay the adoption of this measure until the NQF has endorsed it. We do note, nonetheless, that the CDC recently submitted the quarterly reported HCP COVID–19 vaccination measure for the NQF Fall 2021 measure cycle and intends to submit a biannual reporting version of the COVID–19 vaccination measure for HCP in January 2022.

In addition to the above, we note that the adoption of this measure is consistent with sections 1833(t)(17)(C)(ii) and 1886(b)(3)(B)(viii) of the Act, as incorporated into section 1833(i)(7)(B) of the Act. Pursuant to this authority, the ASCQR Program may select measures that are the same as (or a subset of) the measures for which data are required to be submitted under the Hospital IQR Program. We note that the Hospital IQR Program recently adopted a COVID–19 HCP Vaccination measure for which this data is required to be submitted (86 FR 45374 through 45382).

Comment: One commenter recommended development of a validation process for the COVID–19 Vaccination Coverage Among HCP measure (ASC–20).

Response: We appreciate the commenter's suggestion; we interpret the comment's referral to ''validation'' as what is done under our quality reporting programs where data reported is verified against data contained in original documentation, usually medical records. As discussed in section XVI.3.a.(2).(b). of the CY 2022 OPPS/ASC proposed rule (86 FR 42269), a comparison of two independent databases indicate that the measure is highly reliable and feasible. We agree that it would be preferable to validate COVD–19 vaccination data and will investigate how this could be done in balance with potential burden on ASCs and other facility types for any such process.

Comment: One commenter supported public reporting of this measure and specifically noted support for early publication through the initial shortened reporting period.

Response: We thank the commenter for the support.

Comment: A few commenters expressed concern about reporting frequency. One commenter recommended that CMS reduce reporting frequency from quarterly to twice-yearly or annually to limit reporting burden. Another commenter stated that the reporting frequency would be time-intensive for ASCs with more than one location as those ASCs would need to collect information for staff across multiple facilities.

Response: As stated in the CY 2022 OPPS/ASC proposed rule (86 FR 42270), we believe that it would be ideal to have HCP vaccination data for every week of each month, and we are mindful of the time and resources that ASCs would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least 1 week of each month would be sufficient to obtain a reliable estimate of vaccination levels among an ASC's HCP while balancing the costs of reporting. We believe that reporting at a lower frequency may result in data that is less meaningful and timely to consumers who want to consider HCP vaccination rates as part of their health care decision-making process. Additionally, the CDC has provided a number of resources including a tool called the Data Tracking Worksheet for COVID–19 Vaccination among Healthcare Personnel to help facilities log and track the number of HCP who are vaccinated for COVID–19, which may reduce burden for ASCs. COVID vaccination data would be entered for each HCP in the tracking worksheet, and select a reporting week, and the data to be entered into the NHSN will automatically be calculated on the Reporting Summary.

Comment: One commenter observed that it is difficult for consumers to locate ASC quality data through CMS websites and recommended that CMS prioritize simplifying access to data on this measure due to the ongoing PHE.

Response: We acknowledge the commenters concern regarding availability of ASCQR Program data located currently on the CMS Provider Data Catalog rather than on the Care Compare site and intend to investigate alternate sites for making these data publicly available on a more expedient basis.

Comment: Many commenters expressed concern that the measure reporting requirements are duplicative of other state and federal COVID–19 vaccination reporting requirements and that inclusion of the measure in quality reporting programs is unnecessarily burdensome for ASCs. Some commenters questioned the purpose of the measure given the CMS announcement on September 9, 2021 that the agency will require COVID–19 vaccination of staff within all Medicare and Medicaid-certified facilities.[495] Other commenters noted that they are currently required to report COVID–19 vaccination information to HHS and requested that such reporting might be considered a substitute to reporting proposed for the measure. A few commenters recommended a change to attestation-based reporting to reduce resources and burden required for reporting based on the proposed measure specifications. One commenter observed that time spent on multiple reporting requirements would take away from time available for efforts to improve vaccination coverage. Another commenter requested an analysis of burden and feasibility of data collection prior to adoption of the measure. One commenter recommended re-evaluating the burden of data collection after measure data has been collected for one year.

Response: We appreciate commenters' feedback. We believe that the COVID–19 vaccination of HCP information submitted for this measure will be important as it will be made publicly available for use by Medicare beneficiaries and others in making informed decisions regarding their care including facility choice. We note that most Immunization Information Systems through which commenters may already be required to report vaccination information to HHS do not include the information needed to determine if an immunized person is a healthcare worker. Using the NHSN COVID–19 Vaccination Modules allows tracking vaccination coverage among the patients or HCP in ASCs.[496] We do recognize that this measure may lead to duplicative reporting if ASCs voluntarily report COVID–19 HCP vaccination information to other data reporting systems in addition to this measure requirement via the NHSN, and

[495] Centers for Medicare & Medicaid Services. Biden-Harris Administration to Expand Vaccination Requirements for Health Care Settings. September 9, 2021. Available at: *https://www.cms.gov/newsroom/press-releases/biden-harris-administration-expand-vaccination-requirements-health-care-settings.*

[496] Centers for Disease Control and Prevention. FAQs on Reporting COVID–19 Vaccination Data. August 2021. Available at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/faqs.html.*

we are collaborating with other HHS agencies, including the CDC to minimize reporting burden to the extent feasible.

With regard to measure burden analysis, we refer the commenter to section XXIII.C. of this final rule with comment period, where we discuss the burden associated with the measure. We thank the commenters for the suggestion that the measure be attestation-based and note that any changes to the measure specifications would be proposed through future rulemaking.

Comment: Several commenters observed that there are no currently required measures in the ASCQR Program measure set that require use of NHSN. These commenters observed that this significantly increases reporting burden for this measure because ASCs will be required to enroll in NHSN to submit data for this measure, and NHSN enrollment and account maintenance is a burdensome process. Some of these commenters recommended postponing implementation of the COVID–19 Vaccination Coverage Among HCP measure (ASC–20) to provide more time for ASCs to enroll in NHSN.

Response: We recognize commenters' concerns about operational requirements of reporting and reiterate the availability of resources from the CDC.[497] We believe that given the current COVID–19 PHE as well as the need for continued monitoring and surveillance, it is important to adopt this measure as quickly as possible to allow tracking and reporting of COVID–19 Vaccination Coverage Among HCP measure (ASC–20). As we stated in the CY 2022 OPPS/ASC proposed rule (86 FR 42270) and initially discussed in the CY 2019 OPPS/ASC final rule (83 FR 59115 through 59117), we further recognize that reporting measure data through the NHSN could be more burdensome for ASCs compared to the relative burden for hospitals participating in the Hospital IQR Program and the HAC Reduction Program and especially for freestanding ASCs. We believe, nonetheless, that the public health benefits to having these data available justify the burden of reporting for systems with multiple facilities or locations. While we recognize that there may be some elements of the measure specifications that increase burden for some ASCs, given the impact that the COVID–19 PHE has had on society and the healthcare system, we believe that the benefits, including equity, justify this reporting burden.

Comment: One commenter observed that requiring collection of data at least once monthly is burdensome for ASCs, many of which are small businesses. This commenter further observed that this frequency of data collection does not support the goal of providing patient information because the data will only be publicly reported on a quarterly basis. This commenter recommended aligning data requirements with public reporting frequency.

Response: As stated previously and in the CY 2022 OPPS/ASC proposed rule (86 FR 42270), we believe that it would be ideal to have HCP vaccination data for every week of each month, but are mindful of the time and resources that ASCs would need to report the data. Some COVID–19 vaccines require multiple doses over a period of weeks or months, and we believe that a lower frequency of reporting as recommended by the commenter would likely undercount fully vaccinated HCP within the ASC. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable estimate of vaccination levels among an ASC's HCP while balancing the costs of reporting.

Comment: One commenter recommended aligning with the policy finalized in the FY 2022 IPPS/LTCH PPS final rule in which only the most recent quarter of data will be used for public reporting (as opposed to a rolling 12-month report). Another commenter recommended against averaging monthly data points and suggested only reporting the most recent month's vaccination data to provide the most up-to-date information for patient decision making.

Response: We agree with the commenters; in alignment with the FY 2022 IPPS/LTCH PPS final rule (86 FR 45382) we will not finalize our plan to add one additional quarter of data during each advancing refresh until the point that four full quarters of data is reached and then report the measure using four rolling quarters of data. Instead, we will only report the most recent quarter of data. This would result in more meaningful information that is up to date and not diluted with older data. We emphasize that this modification of our proposal does not affect the data collection schedule established for submitting data to NHSN for the COVID–19 vaccination measure. This would simply update the data that are displayed for the public reporting purposes.

After consideration of the public comments we received, we are finalizing our proposal to adopt the COVID–19 Vaccination Coverage Among HCP measure (ASC–20) with a modification to publicly report only the most recent quarter of data. Additionally, data will also be available for preview by ASCs for 30 days prior to being made publicly available. This will result in more meaningful information that is up to date and not diluted with older data.

4. Changes to Previously Adopted Measures in the ASCQR Program Measure Set

We previously adopted the following measures into the ASCQR measure set: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC–4: All-Cause Hospital Transfer/Admission; ASC–11: Cataracts—Improvement in Patient's Visual Function with 90 Days Following Cataract Surgery; and ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems. For various reasons discussed in sections XVI.B.4.a., XVI.B.4.b., and XVI.B.4.c. of this final rule with comment period, these measures were either paused or suspended from the ASCQR Program.

a. Requirement of Previously Suspended ASC–1, ASC–2, ASC–3, and ASC–4 Measures Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination and Subsequent Years

(1) Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74497 through 74498) where we adopted ASC–1: Patient Burn beginning with the CY 2014 payment determination. This outcome measure assesses the percentage of ASC admissions experiencing a burn prior to discharge. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498) where we adopted ASC–2: Patient Fall beginning with the CY 2014 payment determination (NQF #0266). This measure assesses the percentage of ASC admissions experiencing a fall at the ASC. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498 through 74499) where we adopted ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant beginning with the CY 2014 payment determination (NQF #0267). This outcome measure assesses the percentage of ASC admissions

[497] Centers for Disease Control and Prevention. Reporting Weekly COVID–19 Vaccination Data for Healthcare Personnel Using the National Healthcare Safety Network (NHSN). September 2021. Available at: *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/weekly-covid-reporting-508.pdf.*

experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74499) where we adopted ASC–4: All-Cause Hospital Transfer/Admission beginning with the CY 2014 payment determination (NQF #0265). This outcome measure assesses the rate of ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC.

In the CY 2019 OPPS/ASC proposed rule, we proposed to remove ASC–1, ASC–2, ASC–3, and ASC–4 under measure removal Factor 1—measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made—for the CY 2021 payment determination and subsequent years (83 FR 37198 through 37199). We noted that the ASCQR Program had previously finalized two criteria for determining when a measure is ''topped-out,'' including: (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.10.[498] We presented data demonstrating that each of these four measures met the criteria for topped-out status and stated that we believed their removal from the ASCQR Program measure set was appropriate as there was little room for improvement. In addition, we stated that removal would alleviate the maintenance costs and administrative burden to ASCs associated with retaining the measures. As such, we believed the burden associated with reporting these measures outweighed the benefits of keeping them in the program (83 FR 37198 through 37199).

However, in the CY 2019 OPPS/ASC final rule with comment period, we stated that we had re-evaluated the data due to public comments and reviewed many studies demonstrating the importance of measuring and reporting the data for these measures (83 FR 59118). It became clear to us that these measures are more valuable to stakeholders than we had initially perceived. We agreed that it was important to continue to monitor these types of events, considering the potential negative impacts to patients' morbidity and mortality, to continue to prevent their occurrence and ensure that they remain rare. We acknowledged that these measures provided critical data to beneficiaries and were valuable to the ASC community. We also acknowledged that having measures that apply to all ASCs provides beneficiaries with the most comprehensive patient safety data to use when making decisions about a site of care. Therefore, in the CY 2019 OPPS/ASC final rule with comment period, we did not finalize our proposals to remove ASC–1, ASC–2, ASC–3, and ASC–4 (83 FR 59118). We believed it was more prudent to keep them in the measure set.

However, we also stated in the CY 2019 OPPS/ASC final rule with comment period that we were concerned about some of the data submitted for these measures (83 FR 59119). We explained that the data submission method for these measures, which involved adding specific QDCs onto eligible claims, may impact the completeness and accuracy of the data. Specifically, we were concerned that ASCs lacked the ability to correct the QDC codes that are used to calculate these measures from Medicare FFS claims (83 FR 59119) if the claim had been submitted and processed for payment. We stated that we believed that revising the data submission method for the measures, such as via QualityNet, would address this issue and allow facilities to correct any data submissions errors, resulting in more complete and accurate data (83 FR 59119).

Therefore, we suspended the data collection of ASC–1, ASC–2, ASC–3, and ASC–4 beginning with the CY 2019 reporting period/CY 2021 payment determination (83 FR 59119), but retained these measures in the measure set. Starting with the CY 2021 payment determination, facilities were not required to submit data for these four measures as part of ASCQR Program requirements, even though the measures remained in the ASCQR Program measure set. We stated that as we developed future revisions for the data collected for these measures, we would take into consideration other data submission methods that may allow for the reporting of adverse events across payers and would consider commenters' feedback toward the future updates to the measures (83 FR 59119).

(2) Requirement of ASC–1, ASC–2, ASC–3, and ASC–4 Measures Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination and Subsequent Years

In the CY 2022 OPPS/ASC proposed rule (86 FR 42271 through 42272), we proposed to again require and resume data collection for ASC–1, ASC2, ASC–3, and ASC–4 beginning with the CY 2023 reporting period/CY 2025 payment determination and subsequent years. We proposed that providers would submit data via the HQR System (formerly referred to as the QualityNet Secure Portal). We believe that web-based submission will make reporting easier and more efficient for facilities and will allow facilities to review and correct submitted data until the data submission deadline; our review and corrections policy is discussed in more detail at section XVI.D.2.f. of this final rule with comment period.

We stated that we believed that revising the data submission method for the measures, such as via QualityNet (now known as the HQR System) would address this issue and allow facilities to correct any data submissions errors, resulting in more complete and accurate data (83 FR 59119). Facilities would be able to review and correct their data submissions up to the data submission deadline. As we stated above, we also believe that while these measures have been ''topped-out'', the public continues to believe that it is important to monitor these types of events, considering the potential negative impacts to patients' morbidity and mortality, to continue to prevent their occurrence and ensure that they remain rare.

We refer readers to section XVI.D.1.c.(1). of the CY 2022 OPPS/ASC proposed rule (86 FR 42281), where we discussed the data submission process for web-based measures, for more detail on how ASCs would be expected to submit data.

We received comments on these topics.

Comment: Many commenters supported resuming ASC–1, ASC–2, ASC–3, and ASC–4. Commenters noted that the measures will help improve care and patient experience while minimizing unnecessary burden. Commenters further stated that the measures focus on areas of critical importance for the safety of patients treated in ASCs. One commenter specifically stated the importance of ASC–2 as virtually all patients having outpatient procedures or surgery receive sedatives, anesthetics and/or pain

[498] In the CY 2019 OPPS/ASC proposed rule, we also clarified how we calculated the TCOV for ASC–1, ASC–2, ASC–3, and ASC–4, which assess the rate of rare, undesired events for which a lower rate is preferred. Typically, for measures for which a higher rate is preferred, we determine the TCOV by calculating the truncated standard deviation (SD) in performance divided by the truncated mean of performance (the mean of positive events). For these four measures, we employed an alternate methodology utilizing the mean of *non-adverse* events in our calculation of the TCOV. This substitution resulted in a TCOV that was comparable to that calculated for other measures and allowed us to assess rare event measures by still generally using our previously finalized topped-out criteria. For more information, see 83 FR 37196 through 37197.

medications as a routine part of their care, which in turn increases the likelihood of a fall. This commenter also expressed the importance of ASC–4 and agreed that the rate of such transfers and admissions should be monitored to flag where improvements in practices or patient selection criteria are needed, given that ASCs can take steps to reduce the incidence of such events. One commenter supported the measures and recommended that physical therapists be consulted for falls as part of ASC–2.

Response: We thank the commenters for their support and agree that resuming ASC–1, ASC–2, ASC–3, and ASC–4 so that collecting information on the incidence of these patient safety events and making the information publicly available is important.

Comment: A few commenters did not support resuming reporting of the measures. Some commenters noted that the measures no longer maintain NQF endorsement and recommended that NQF endorsement be restored before reporting resumes. A few commenters stated that the measures were no longer required for reporting because they were topped out and rare, and their reintroduction into the program is unlikely to offer meaningful or actionable data for ASCs.

Response: While it is true that these measures are no longer NQF endorsed, endorsement was not removed, but instead lapsed as the measure steward made the decision not to submit the measures for reconsideration of endorsement. Data for these measures continues to be collected and reported under the Ambulatory Surgical Center Association (ASCA)'s benchmarking effort for their members. Thus, we believe that these measures continue to meet the statutory requirement of consensus.

With regard to the measures being topped out, as we stated in the CY 2022 OPPS/ASC proposed rule (86 FR 42271) and initially discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59118), we re-evaluated the measure data and reviewed many studies demonstrating the importance of measuring and reporting the data for these measures. ASC–1, ASC–2, ASC–3, and ASC–4 are measures that provide information to consumers about overall quality and safety within an ASC compared to other measures in the ASCQR Program measure set that focus on the quality and safety of specific procedures or events that may take place in an ASC setting. Therefore, we believe these measures are valuable and that it is important to continue to monitor these types of events, given the potential negative impacts to patients' morbidity and mortality, in order to continue to prevent their occurrence and ensure that they remain rare.

Comment: Some commenters requested clarification on the reporting population and noted that previously, these claims-based measures were reported only for Medicare FFS patients, but could be expanded to all patients. A few of these commenters recommended expanding reporting to all patients to increase transparency and accountability of the measures. One commenter stated that there have been problems with the batch submission function for reporting the measure data in the HQR platform and requested an update from CMS on how this issue has been addressed. One commenter requested clarification on what is meant by CY 2023 reporting period/CY 2025 payment determination. The commenter noted that it understood the first year of reporting was data collection, the second year was data reporting, and the third year was payment impact. If data collection is required to resume in January 2022, the commenter notes this would be challenging to implement. One commenter expressed a preference for reporting the measures via QualityNet instead of HQR.

Response: We appreciate commenter questions regarding the reporting population. As commenters noted, these measures were previously claims-based measures and applied to Medicare FFS patients. However, we would like to clarify that because the measures have been reintroduced as web-based, they will apply to all ASC patients in accordance with the measure developer's specifications, which define the denominator as all ASC admissions.[499] As stated in the CY 2022 OPPS/ASC proposed rule (86 FR 42281), ASC–1, ASC–2, ASC–3, and ASC–4 were proposed for reintroduction as measures submitted via an online data submission tool. In the CY 2014 OPPS/ASC final rule (78 FR 75113), we discussed data submission for measures submitted via web-based reporting tools and stated that hospitals and ASCs would submit aggregate-level data through the CMS web-based tools for measures with such specifications. We agree with the commenters that reporting for all ASC patients will promote transparency and accountability for the measure data. With regard to batch submission issues, we appreciate the comment and note that systems changes are in progress for restoring the batch submission functionality that was compromised with the implementation of new infrastructure. We acknowledge the commenter's concern about reporting beginning in January 2022 and note that data collection will resume beginning CY 2023 with reporting in CY 2024 and payment in CY 2025. Many ASCs are familiar with reporting for these measures and we believe it is appropriate to finalize the measures for inclusion in the ASCQR Program beginning CY 2023. We clarify that for reporting purposes, reporting via the HQR System and QualityNet are equivalent. Reporting via HQR allows ASCs to make corrections during the data submission period which was not possible in the past if an ASC identified an erroneous or missing QDC on a claim that had already been submitted and processed, reduces the amount of time and resources required to submit measure data, and simplifies the requirements of the ASCQR Program by streamlining the number of methods required for quality measure data submission.

After consideration of the public comments we received, we are finalizing this proposal as proposed with the clarification regarding the population for which data will be collected.

b. ASC–11: Cataracts—Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536) Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75129) we finalized the adoption of the ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure.[500] This measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery (78 FR 75129) via the administration of pre-operative and post-operative visual function surveys.

During the CY 2014 OPPS/ASC rule cycle, some commenters expressed concern about the burden of collecting pre-operative and post-operative visual

[499] Ambulatory Surgical Center Quality Collaboration. Quality measures developed and tested by the ASC Quality Collaboration (ASC QC). Accessed at: *https://higherlogicdownload.s3.amazonaws.com/ASCACONNECT/1b34f1a1-0180-4005-9507-902fdf8f242e/UploadedImages/ASC_Quality_Collaboration/Documents/2019-Summary-ASC-QC-Measures.pdf.*

[500] We note that this measure was endorsed by the NQF under NQF #1536 at the time of adoption but has subsequently had its endorsement removed.

function surveys (78 FR 75129 and 75138). In response to those comments, we modified our implementation strategy in a manner that we believed would significantly minimize collection and reporting burden (78 FR 75129). Specifically, we applied a sampling scheme and a low case threshold exemption to address commenters' concerns regarding burden (78 FR 75138 through 75139). With those changes, we intended to decrease burden and facilitate data reporting by allowing random sampling of cases when volume is high, instead of collecting information for all eligible patients (78 FR 75138 through 75139). For further details, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75129; 75138 through 75139).

Shortly thereafter, we became concerned about the use of what we believed at the time were inconsistent surveys to assess visual function. The measure specifications allowed for the use of any validated survey and we were unclear about the impact the use of varying surveys might have. Therefore, we issued guidance stating that we would delay the implementation of ASC–11.[501]

Subsequently, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985), we finalized our proposal to exclude ASC–11 from the CY 2016 payment determination measure set, and for subsequent years (79 FR 66984). In addition, we finalized allowing ASCs to voluntarily report ASC–11 data for the CY 2015 reporting period/CY 2017 payment determination and subsequent years (79 FR 66984).

(2) ASC–11 Measure Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination and for Subsequent Years

In the CY 2022 OPPS/ASC proposed rule (86 FR 42272 through 42273), we stated that we believed it would be appropriate to require that ASCs report on ASC–11. We stated that ASCs have had the opportunity for several years to familiarize themselves with ASC–11, prepare to operationalize it, and opportunity to practice reporting the measure since the CY 2015 reporting period/CY 2017 payment determination. We noted that a small number of facilities have consistently reported data for this measure and these data have been made publicly available. While we previously had concerns regarding the use of different surveys to assess visual function (79 FR 66984), using different surveys has been found to not result in inconsistencies; the allowable surveys are scientifically validated and provide comparable results.[502] Of 16 different cataract surgery outcome questionnaires it has been demonstrated that all were able to detect clinically important change.[503]

In the CY 2022 OPPS/ASC proposed rule (86 FR 42272 through 42273), we proposed to require reporting for the NQF-endorsed ASC–11 measure beginning with the CY 2023 reporting period/CY 2025 payment determination and subsequent years. As we stated in the CY 2014 OPPS/ASC final rule with comment period, as well as the CY 2015 OPPS/ASC final rule with comment period and consistent with the MAP recommendation, we continue to believe that this measure ''addresses a high-impact condition'' that is not otherwise adequately addressed in our current measure set (78 FR 75129 and 79 FR 66984, respectively). Moreover, ASC–11 serves to drive coordination of care (78 FR 75129 and 79 FR 66984) in multiple ways, including the operational requisites for conducting and sharing the results of the surveys as well as providing opportunities for care coordination as well as direct patient feedback.

We refer readers to section XVI.D.1.c.(1). of this final rule with comment period for information about submitting data via a CMS web-based tool.

We received comments on these topics.

Comment: A few commenters supported our proposal to require the reporting of the ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure.

Response: We thank the commenters for their support. We agree that this measure has considerable merit as a patient-reported outcome measure for a large volume procedure for the ASC setting. We emphasize the value of this measure and continue to believe that ASC–11 addresses a high-impact condition and that it provides opportunities for care coordination and direct patient feedback.

Comment: Many commenters expressed concern about making this measure mandatory, stating that because the ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure is not currently mandatory, many facilities have not been ''practicing'' reporting it. One commenter additionally noted that this measure would be difficult to coordinate between physicians and ASCs.

Response: We thank the commenters for their feedback. We recognize from the challenges shared in the public comments, and discussed herein, that while the measure has been voluntary and available for reporting since the CY 2015 reporting period, a number of facilities have reported data for this measure and those that have reported it have done so consistently. To address commenters' concerns, we are finalizing to require ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2025 reporting period/CY 2027 payment determination, instead of our originally proposed data collection beginning with the CY 2023 reporting period. We believe the 2-year extension from our originally proposed timeline of the CY 2023 reporting period/CY 2025 payment determination, will provide facilities with sufficient time to provide staff training and operationalize the measure for successful reporting in the ASCQR Program.

Comment: Many commenters did not support the requirement for mandatory reporting of the ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure, citing concerns about the operational complexity of collection and sharing data for the measure across physician and ASC settings. Many commenters believed administering surveys and tracking responses for the ASC–11 measure would be burdensome. Specifically, many commenters were concerned that this measure was developed as a physician-level measure, and related data would be generated and obtained in a physician's medical record and/or EHR that is not necessarily accessible by ASCs. One commenter expressed concern about being able to

[501] The implementation was first delayed by 3 months—from January 1, 2014 to April 1, 2014, for the CY 2016 payment determination, via guidance issued December 31, 2013. Available at: *https://qualitynet.cms.gov/asc/notifications*. Because of continuing concerns, on April 2, 2014, we issued additional guidance stating that we would further delay the implementation of the measure from April 1, 2014 to January 1, 2015 for the CY 2016 payment determination. Available at: *https://qualitynet.cms.gov/asc/notifications*.

[502] McAlinden C, Gothwal VK, Khadka J, Wright TA, Lamoureux EL, Pesudovs K. A head-to-head comparison of 16 cataract surgery outcome questionnaires. Ophthalmology. 2011 Dec;118(12):2374–81. doi: 10.1016/j.ophtha.2011.06.008. Epub 2011 Sep 25. PMID: 21945088.

[503] McAlinden C, Gothwal VK, Khadka J, Wright TA, Lamoureux EL, Pesudovs K. A head-to-head comparison of 16 cataract surgery outcome questionnaires. Ophthalmology. 2011 Dec;118(12):2374–81. doi: 10.1016/j.ophtha.2011.06.008. Epub 2011 Sep 25. PMID: 21945088.

share data between facilities and clinicians within the bounds of HIPAA.

Response: We thank the commenters for their input, and we acknowledge their concerns. Our overarching goal for proposing the adoption of the ASC–11 measure is to encourage the coordination of care across health care settings, providers, and suppliers as frequently as possible (78 FR 75126). We aim to see ASCs, ophthalmologists, and other clinicians such as optometrists, actively and routinely engaged in exchanging information to better communicate and coordinate the care of patients. We understand, however, that it may be difficult and complex to share data generated in different settings. We believe the 2-year extension from our originally proposed timeline of the CY 2023 reporting period/CY 2025 payment determination will provide ASCs with sufficient time for clinics and staff to address potential issues regarding extracting and sharing patient data. The 2-year extension will also allow facilities to prepare and update systems and technology, and prevent additional reporting burden during the COVID–19 pandemic. Additionally, we recognize that the ASC–11 measure is currently tested at the clinician-level and not at the facility-level. We will continue to monitor this measure and will address potential updates, as appropriate.

We note that the HIPAA Privacy Rule permits a covered entity to disclose PHI to another covered entity for certain health care operations of the recipient covered entity. Additionally, a covered entity may disclose PHI to a business associate and to allow a business associate to create, receive, maintain, or transmit PHI on its behalf, provided that the parties have a Business Associate Agreement (BAA) that meets the requirements of 45 CFR 164.504(e) and permits the business associate to use or disclose PHI only as permitted or required by its BAA or as required by law. The BAA must, among other things, establish the permitted and required uses and disclosures of PHI by the business associate.

Comment: A few commenters requested the measure remain voluntary because they believe that obtaining the data 90 days after outpatient surgery would be difficult. Commenters raised concerns that surveying patients and getting appropriate responses in this timeline may result in a resource burden for ASCs.

Response: We thank the commenters for their feedback and acknowledge their concerns. We highly encourage hospitals, ophthalmologists, and other clinicians to actively and routinely engage in exchanging information to better communicate and coordinate the care of patients to promote quality of care. We acknowledge complexity of administering and sharing data for ASC–11 across different settings; however, we emphasize the value of this measure and continue to believe that ASC–31 addresses a high-impact condition and provides opportunities for care coordination and direct patient feedback. We believe the 2-year extension from our originally proposed timeline of the CY 2023 reporting period/CY 2025 payment determination, will provide facilities with sufficient amount of time to provide staff training and operationalize the measure for successful reporting in the ASCQR Program, including implementing methods to procure appropriate data 90 days after outpatient surgery.

Comment: A few commenters raised concerns with measure specifications, especially the lack of specificity around administration of the survey to ensure consistency between the pre- and post-operative surveys as well as comparability of the measure across ASCs. One of these commenters disagreed with the use of the study cited, noting that it reviewed responsiveness of different questionnaires and not comparison of agreement across different questionnaires.

Response: We thank commenters for their feedback. We recognize commenter concerns related to the measure specifications. However, we respectfully disagree with the assessment of the McAlinden et al. study cited.[504] While that study indicated that the use of one survey is ideal for measuring visual function outcomes, we reiterate that their findings showed that the use of different surveys did not result in inconsistencies and we maintain that it is appropriate for inclusion in the ASCQR Program measure set. We reiterate our belief that ASC–11 provides a valuable opportunity to hear patient feedback on visual function outside of the clinical setting. After consideration of the public comments we received, we are finalizing the proposal to require ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery with modification. To address commenters' concerns, we are finalizing to require ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2025 reporting period/CY 2027 payment determination, instead of our originally proposed data collection beginning with the CY 2023. We believe the two-year extension from our originally proposed timeline of the CY 2023 reporting period/CY2025 payment determination, will provide ASCs with sufficient amount of time to implement coordination strategies between the surgeon and the ophthalmologist, provide staff training, and operationalize the measure for successful reporting in the ASCQR Program.

c. Requirement of ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With Voluntary Reporting in CY 2023 Reporting Period and Mandatory Reporting Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination and for Subsequent Years

(1) Background

We previously adopted the ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures to assess patient experience with care following a procedure or surgery in an ASC. These survey-based measures rate patient experience as a means for empowering patients and improving the quality of their care (82 FR 59450). For further details on this measure, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79803 through 79817), in which we adopted these measures beginning with the CY 2020 payment determination.

Subsequently, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 49450 through 49451), we delayed implementation of ASC–15a–e for the ASCQR Program beginning with the CY 2020 payment determination due to lack of sufficient operational and implementation data. At that time, we believed that our ongoing National OAS CAHPS Survey voluntary reporting program for the survey, which began in January 2016 [505] and is unrelated to

[504] McAlinden C, Gothwal VK, Khadka J, Wright TA, Lamoureux EL, Pesudovs K. A head-to-head comparison of 16 cataract surgery outcome questionnaires. Ophthalmology. 2011 Dec;118(12):2374–81. doi: 10.1016/j.ophtha.2011.06.008. Epub 2011 Sep 25. PMID: 21945088.

[505] Participation in the program is open to any interested Medicare-certified Hospital Outpatient Departments (HOPDs) and free-standing ambulatory surgery centers (ASCs). More information on the National OAS CAHPS Survey voluntary reporting program is available at: *https://oascahps.org/General-Information/National-Implementation* and *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS/OAS-CAHPS.*

either the Hospital OQR Program or ASCQR Program, would provide valuable information moving forward. Specifically, we wanted to use the information from the National OAS CAHPS Survey voluntary reporting program to: (1) Ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; (2) reaffirm the reliability of national implementation of OAS CAHPS Survey data; and (3) appropriately account for the burden associated with administering the survey in the outpatient care setting.

Having had the opportunity during the delayed implementation to investigate the concerns about patient response rates and data reliability, we believe that patients are able to respond to OAS CAHPS Survey questions, and that those responses are reliable based on experience collecting voluntary data for public reporting since CY 2016 (available at *https://www.medicare.gov/care-compare/*). We reaffirm that the OAS CAHPS Survey-based measures assess important aspects of care where the patient is the best or only source of information (81 FR 79803). Regarding the burden associated with the survey, we believe that measuring patient experience provides important information to ASCs and patients, especially for assessing the quality of care provided at an ASC (82 FR 59450). Furthermore, in section XVI.D.1.d.(2). of the CY 2022 OPPS/ASC proposed rule (86 FR 42282 through 42284), we proposed additional collection modes using a web-based module (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents) for administering the survey, which would be available beginning in CY 2023 under the ASCQR Program and for subsequent years.[506] We believe these additional collection modes would further address some burden concerns raised during the CY 2017 OPPS/ASC final rule with comment period (81 FR 59450) because the web-based modules may produce similar results, but at lower costs of collection.[507] As we stated in the CY 2018 OPPS/ASC final rule with comment period, we continue to believe that implementation of these measures will enable objective and meaningful comparisons between ASCs (82 FR 59450) and that patient experience of care data are valuable in assessing the quality of care provided at an ASC and assisting patients in selecting a provider for their care (82 FR 59450).

In the CY 2022 OPPS/ASC proposed rule (86 FR 42273), we proposed to restart the ASC–15a–e measures by proposing to link reporting of measure data with payment determinations as part of the ASCQR Program beginning with the CY 2024 reporting period/CY 2026 payment determination. Specifically, for the ASCQR Program, we proposed voluntary data collection and reporting beginning with the CY 2023 reporting period, followed by mandatory data collection and reporting beginning with the CY 2024 reporting period/CY 2026 payment determination. As noted above, the National OAS CAHPS Survey voluntary reporting program is independent of the ASCQR Program and the Hospital OQR Program. ASCs that voluntarily report the OAS CAHPS Survey-based measures during the CY 2023 reporting period would do so as part of the ASCQR Program until mandatory reporting begins. The reporting process for ASCs to submit OAS CAHPS Survey data would remain unchanged, that is, ASCs would submit OAS CAHPS Survey data through their vendors who would submit these data to CMS as appropriate. We refer readers to section XVI.D.1.d. of this final rule with comment period for additional information regarding the form, manner, and timing for reporting the ASC–15a–e survey-based measures.

We initially considered a 2-year voluntary period, that is, the CY 2023 and CY 2024 reporting periods, because we believed that ASCs may require additional preparation time for OAS CAHPS Survey implementation including contracting with OAS CAHPS vendors. We also considered the challenges that many ASCs may have experienced during the COVID–19 pandemic and the additional operational constraints that they may still be experiencing. However, since voluntary reporting, including the two new modes of data collection we proposed in section XVI.D.1.d.(2) of the CY 2022 OPPS/ASC proposed rule (86 FR 42282 through 42284), will be available in 2022 as part of the National OAS CAHPS voluntary reporting program, we proposed 1 year of voluntary reporting as part of the ASCQR Program for the CY 2023 reporting period. As described in the NPRM, we believed that ASCs would have sufficient time to familiarize themselves with OAS CAHPS measures and OAS CAHPS vendors prior to mandatory reporting in the CY 2024 reporting period/CY 2026 payment determination and for subsequent years.

We refer readers to section XVI.D.1.d. of the CY 2022 OPPS/ASC proposed rule (86 FR 42282) for our related proposals regarding the form, manner, and timing for reporting the ASC–15a–e Survey-based measures.

We also refer readers to section XV.B.5.a. of the CY 2022 OPPS/ASC proposed rule (86 FR 42246 through 42247) where we proposed to restart this measure in the Hospital OQR Program. We received comments on these topics.

Comment: A few of commenters supported voluntary reporting of the ASC–15a–e: OAS CAHPS Survey-based measures for the CY 2023 reporting period/CY 2025 payment determination for the ASCQR Program. One commenter expressed support for CMS' efforts to develop the OAS CAHPS Survey-based measures and is pleased the OAS CAHPS Survey addresses the experience of surgical care received at both HOPDs and ASCs, which the commenter believes will support consumers' ability to compare facilities.

Response: We thank the commenters for their support for the voluntary reporting of the OAS CAHPS Survey-based measures as part of the ASCQR Program. We believe that these survey-based measures will be useful to assess aspects of care where the patient is the best or only source of information, and to enable objective and meaningful comparisons between ASCs. We believe reporting for these measures as part of the ASCQR Program would provide meaningful information to patients and provide ASCs the opportunity to experience reporting as part of the ASCQR Program. As the OAS CAHPS Survey results are available, they will be made publicly available along with other ASCQR measure data (currently on the CMS Provider Data Catalog), which is made available to inform consumers and encourage healthcare facilities to make continued improvements in care quality.

Comment: One commenter did not support the 1-year voluntary reporting period, but generally supported the inclusion of the OAS CAHPS Survey and recommended the 2-year period that CMS had initially considered. Another commenter urged CMS to delay voluntary implementation under the ASCQR Program until CY 2024. These commenters expressed concerns about staffing shortages and the cost and time to update systems to accommodate the measure during the unprecedented challenges posed by the COVID–19

[506] We note that the mixed modes will be available as part of the National OAS CAHPS voluntary reporting program beginning in CY 2022.

[507] Bergeson SC, Gray J, Ehrmantraut LA, Hays RD. Comparing Web-based with Mail Survey Administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Clinician and Group Survey. Prim Health Care. 2013 Sept; doi: 10.4172/2167–1079.1000132. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3783026/*.

pandemic, and the requirements imposed by other federal regulations, which they believe warrant extended preparation time for OAS CAHPS Survey implementation.

Response: We thank the commenters for their general support for inclusion of the OAS CAHPS Survey-based measures in the ASCQR Program and understand preference to delay the start of voluntary reporting based on concerns about COVID–19 and the need to accommodate ASCs while our nation works through the unprecedented COVID–19 pandemic. We also understand how delaying the implementation of the OAS CAHPS Survey-based measures as part of the ASCQR Program will afford ASCs additional time to address staffing shortages, prepare for additional federal regulations, and respond to the public health emergency caused by COVID–19. Due to the impact of the ongoing PHE for COVID–19 on ASC facilities, we are delaying the start of mandatory reporting by one year, to begin with the CY 2025 reporting period/CY 2027 payment determination under the ASCQR Program. Voluntary reporting will still be available as part of the ongoing program for voluntarily reporting the National OAS CAHPS Survey.

Comment: A couple commenters supported CMS' proposal to require mandatory reporting of the OAS CAHPS Survey-based measures within the ASCQR Program beginning with the CY 2024 reporting period/CY 2026 payment determination. One commenter noted the belief that the OAS CAHPS Survey-based measures will help facilities identify areas of strengths and areas of improvement for patient experience, while another believed the OAS CAHPS Survey-based measures would provide more real time quality data to inform ASCs' decision-making.

Response: We thank the commenters for their support for mandatory reporting of the OAS CAHPS Survey-based measures. We believe the measures will provide facilities with important feedback and support their ability to improve patient experience.

Comment: A few commenters recommended delaying mandatory implementation of the survey-based measures. Among commenters concerns were the ongoing COVID–19 pandemic and current staffing shortages.

Response: We thank the commenters for their feedback. We understand the commenters' requests to delay the mandatory implementation of the OAS CAHPS Survey-based measures and their concerns regarding the on-going public health emergency and staffing. We agree that delaying mandatory reporting of the OAS CAHPS Survey-based measures while ASCs respond to the COVID–19 pandemic and related staffing shortages is appropriate. As a result, we are delaying the start of mandatory reporting as part of the ASCQR Program until the CY 2025 reporting period/CY 2027 payment determination. Voluntary reporting will still be available as part of voluntary National OAS CAHPS Survey reporting.

Comment: A few commenters opposed mandatory reporting of the OAS CAHPS Survey-based measures and expressed concern regarding the financial and administrative burden of OAS CAHPS on ASCs. One commenter expressed concern that the cost of implementing the survey-based measures could exceed the 2 percent penalty for failing to meet the ASCQR Program requirements. Another commenter believed that ASCs may decide to stop providing services due to the cost of survey implementation. Other commenters opposed the OAS CAHPS Survey-based measure because they believe that ASCs are inadequately compensated by CMS to support the additional cost of the administration of the survey and OAS CAHPS Survey could force ASCs to reconsider remaining open or closing. Another commenter suggested that mandatory reporting of OAS CAHPS Survey may cause some small ASCs to stop reporting.

Response: We thank the commenters for their feedback. While there are administrative and financial burdens associated with implementing the OAS CAHPS Survey-based measures in the ASCQR Program, we believe the benefits of capturing patient experience of care data in the ASC setting outweigh the burdens. In selecting measures for the ASCQR Program, we weigh the relevance and utility of measures against the potential burden to ASCs resulting from the measure's adoption, and we believe the OAS CAHPS Survey-based measures are a vital source of information in assessing the quality of care provided at ASCs.

We post the list of the approved OAS CAHPS Survey vendors on *https://oascahps.org*, and we encourage ASCs to contact vendors for cost and service information pertaining to survey administration as there may be differences among vendors and multiple modes of conducting the survey provide greater economic choice.

In addition, we proposed additional modes to collect the OAS CAHPS Survey-based measures, which we expect to reduce the future cost of administration. We refer readers to the Protocols and Guidelines Manual for the OAS CAHPS Survey (*https://oascahps.org/Survey-Materials*) for materials for each mode of survey administration.

While we did not propose solely digital modes of conducting the OAS CAHPS Survey in the CY 2022 OPPS/ASC proposed rule, we are analyzing whether a web-only or digital-only format would be appropriate for the OAS CAHPS Survey-based measures, which could potentially further reduce the costs of administering the survey. We also refer to readers to section XVI.D.1.d.(2).(a) of this final rule with comment period and below where we finalize a reduced number of required surveys to meet the time, form and manner requirements, which should further reduce the expected burden on ASCs.

Comment: A few commenters requested we delay mandatory reporting of the OAS CAHPS Survey-based measures because of perceived issues with the CPT coding consistency across vendors and the IT requirements to maintain CPT and DRG code lists.

Response: We thank the commenters for their feedback. We interpret the commenters' concern to mean that there may be confusion over which patients would be eligible to be surveyed as part of the OAS CAHPS Survey reporting. The OAS CAHPS Survey is administered to all eligible patients—or a random sample thereof—who had at least one outpatient surgery/procedure during the applicable month. We acknowledge the concern about the use of CPT codes, including those for procedures that patients may not perceive as surgery. However, we note that many CPT codes have been excluded from inclusion in the OAS CAHPS Survey, including services like application of a cast or splint, in order to ensure that only patients receiving applicable procedures are surveyed.[508]

CMS recognizes in some cases there could be delays in getting the CPT codes updated in the patient record and transmitted to the survey vendor in a timely manner. Under the current protocol for survey administration, CMS allows survey vendors to work with HOPD and ASC facilities to identify alternatives ways to identify the patient records for outpatient surgery or diagnostic procedures that were performed in eligible HOPDs or ASCs (as identified by the facility-level eligibility criteria). Vendors can submit exception requests to request alternative

[508] *See* Announcements (*oascahps.org*) where updates on Survey specifications and guidelines are available.

methods for identifying the eligible population. We also note that the current protocol for survey administration allows for late start requests for situations in which the complete patient records are not available within the target window of time for survey administration. Vendors can submit late start requests when the patient data file is received more than 26 days after the sample month. This allows for flexibility in situations when the CPT codes are not available initially but can be updated. Further, sampling is allowed to proceed if 90 percent of the patient records have CPT codes.

Any updates to the Survey Specifications and Guidelines will be available on the OAS CAHPS Survey website (*https://oascahps.org/*).

Comment: Many commenters expressed concern regarding the length of the survey, recommending that the survey should be significantly shortened to focus on actionable aspects of the patient experience and to encourage higher response rates amongst patients. Specifically, some commenters recommended that a revised survey should include 5–10 questions.

Response: The OAS CAHPS Survey is comparable in length and survey response rate to other patient experience of care surveys. The survey instrument was developed to provide a more complete picture of the patients' experience of care in the ASC setting. The 24 core questions of the OAS CAHPS Survey are either directly actionable (that is, give feedback to ASCs/hospitals) or inform the need for patients to answer subsequent questions that are actionable. We note that the survey results to date do not show that respondents are terminating the interview before the last question, which would be an indication of respondent fatigue for a survey that is too long. Based on the most recently received national implementation data for voluntary reporting, the nonresponse due to terminated interviews is less than 1 percent.

Implementing the OAS CAHPS Survey-based measures in the ASCQR Program will enable patients to compare patient experience of care data across multiple ASCs as part of their healthcare decision-making. In addition, we believe implementing these measures in the ASCQR Program will incentivize ASCs to factor patient experience of care into their quality improvement efforts more proactively. However, we also acknowledge these commenters' concerns about the length of the OAS CAHPS Survey and will continue to consider whether refinement would be appropriate.

Comment: A commenter opposed mandatory reporting and expressed concern about the national data reliability of the OAS CAHPS Survey.

Response: We thank the commenter for its comments. We disagree that OAS CAHPS Survey does not have national data reliability. OAS CAHPS Survey data has been collected as part of the voluntary National OAS CAHPS Survey since 2016. Based on our experience through this reporting, we are able to: (1) Ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; (2) reaffirm the reliability of national implementation of OAS CAHPS Survey data; and (3) appropriately account for the burden associated with administering the survey in the outpatient setting. Unit-level reliability analysis of the publicly reported composites for OAS CAHPS are well above the .70 cut-off typically used to assess reliability of a measure.

Comment: One commenter expressed concern that the OAS CAHPS Survey uses the Top-Box methodology rather than the net promoter score (NPS) to measure patient satisfaction, which the commenter believes provides less meaningful data on measuring patient satisfaction. Another commenter noted that the response scale and compact scoring distribution may limit the ability for consumers to differentiate high and low quality providers.

Response: We thank the commenters for their feedback. In 2014, field-tested data were evaluated and analyzed to identify item-level refinements necessary for the survey instrument. The field test psychometric analysis included evaluations of individual items and composite item sets. Individual items were analyzed to report item-level missing data and item response distributions (including ceiling and floor effects), which included response variance. Composite item sets were analyzed using factor analysis and item response theory (IRT) analysis to assess dimensionality, discriminability, dimensional coverage, and subgroup response differences. Internal consistency statistics (reliability) and correlational checks for composite validity were performed to evaluate the final composite item sets. The item-level recommendations for the field test were based on the findings from the factor analyses, the internal consistency checks, and the IRT analysis. As a result, 10 questions were recommended for deletion. Reliability of the remaining measures was assessed using the Cronbach's alpha coefficient, with an estimate range from zero to one. An estimate of zero indicated no measurement consistency and one indicates perfect consistency. The cutoff criterion for the examination was 0.70, which indicated adequate consistency.[509] The composites analytically derived maintained adequate internal consistency even when reduced to Top-Box scoring and across the facility types and modes of administration. Based on the rigorous testing that was undertaken during the development process, we believe the OAS CAHPS Survey, and measure scores derived therefrom, are both reliable and valid. Therefore, we believe that the scoring used in the OAS CAHPS Survey measures is appropriate. Updated unit-level reliability analysis of the publicly reported composites during voluntary national implementation continues to be well above the .70 cut-off for reliability.

Comment: A couple of commenters opposed the OAS CAHPS Survey-based measures due to the lack of NQF endorsement. The commenters encouraged CMS to pursue NQF endorsement of these measures before the OAS CAHPS Survey is required in order to ensure all stakeholders are given insight into the measure and to guarantee that it is fair and accurate.

Response: We thank the commenters for their comments. As we have stated in prior rules (81 FR 79808 and 82 FR 59433), section 1833(t)(17)(C)(i) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or the NQF specifically. Further, under section 1833(i)(7)(B) of the Act, section 1833(t)(17)(C)(i) of the Act applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. While we strive to adopt NQF-endorsed measures when feasible and practicable, we believe the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, stakeholder input via a Technical Expert Panel (TEP), review by the MAP, broad acceptance and use of the measure, and public comments.

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79803 through 79824) for a fuller discussion of the rigorous testing applied to the OAS CAHPS Survey and our belief that it is appropriate for the ASCQR Program.

[509] Dillman, D. A. 1978. Mail and Telephone Surveys: The Total Design Method. New York: Wiley & Sons.

Comment: A commenter expressed concern regarding the ophthalmology-specific ASCs and the number of OAS CAHPS Survey questions regarding ophthalmology as many ophthalmology patients are unable to regularly check their email due to their limited vision.

Response: We appreciate the commenters concern regarding the well-being of patients who undergo eye procedures. However, we do not believe completing the survey poses an additional hardship on ophthalmology patients. After a patient has a surgery or procedure, the survey can be completed up to 6 weeks (42 days) following the invitation to complete the survey. Additionally, we provide different modes of survey administration that would allow for greater accessibility by patients completing the survey, including telephonic surveying, which may provide greater accessibility to individuals with limited vision. We believe that the OAS CAHPS Survey assesses patient experience of care for outpatient surgical procedures, and therefore, takes the outpatient/ambulatory setting into account and captures information about the appropriate experiences of care for this setting, including ophthalmology patients. Based on the results of the 2019 OAS CAHPS mode experiment, the response rates for ophthalmology patients were not significantly different from other types of outpatients. However, we will monitor this issue to ensure that the response data does not indicate that ophthalmology patients are not outliers to the rest of patients surveyed.

Comment: A few commenters opposed mandatory reporting of the OAS CAHPS Survey because of concerns regarding the patient response rate.

Response: We thank the commenters for their feedback. We agree with commenters that patient response is largely out of the control of the facility. However, we note that we did not propose to penalize ASCs for patients' decision not to complete the survey. Payment implications under the ASCQR Program are tied to the successful and timely reporting of required quality measure data. An ASC will not receive a payment reduction based on performance under the OAS CAHPS Survey-based measures if the ASC administers the survey according to the OAS CAHPS Survey Protocol and Guidelines Manual [510] and submits that data to CMS by the data submission deadline, regardless of the number of completed surveys the facility receives. Results will be used for public reporting only.

Comment: A commenter expressed concern for ASC departments that will incur multiple sets of patient experience results and recommended that the OAS CAHPS Survey only apply to services where anesthesia is used.

Response: We thank the commenter for its suggestion; however, we believe that the OAS CAHPS Survey is appropriately scoped to provide patients and facilities meaningful data on the services provided by ASCs and not just those that require anesthesia.

Comment: A commenter requested that we do more to ensure correct attribution of the patient experience and requested we provide evidence of the OAS CAHPS Survey's reliability before it requires survey administration, which could reduce the reliability of the results and negatively impact data-driven decision making.

Response: We thank the commenter for its feedback. The OAS CAHPS Survey is used to obtain data on a patient's experience of care received from a facility. While there is always potential that a patient gets confused, we believe that the OAS CAHPS Survey is focused on patients' experience of care received for their ambulatory surgery or procedure. A physician/surgeon who performs surgeries/procedures at a facility is a member of that facility with both rights and responsibilities. We believe it is the facility's responsibility to ensure that someone whether the doctor, nurse, or other facility staff member, provide patients with information about preparing for their procedure, about the procedure itself, as well as what to expect following the procedure/surgery. Therefore, we believe it is appropriate to include these important communications with patients in the OAS CAHPS Survey and believe experience with the provider attributed to the facility is appropriate.

Further, we believe that the information provided in the OAS CAHPS Survey ''Instructions'' is sufficient to inform the patient regarding the purpose of the OAS CAHPS Survey and provides sufficient instruction and details for the patient to correctly identify and relate the survey to the facility and from which that patient received the procedure. CMS began developing the OAS CAHPS Survey in 2012 using the principles and guidelines established by the Agency for Healthcare Research and Quality's (AHRQ) CAHPS program and AHRQ approved this instrument as a CAHPS survey in February 2015.[511]

Comment: A commenter sought information on whether the OAS CAHPS Survey may have a positive, indirect effect on the way physicians communicate with patients and recommended an on-going evaluation of the effectiveness of the survey to understand the benefit and whether the survey data is informing improvements in care delivery. The commenter also requested additional information on patient experience of care in the HOPD and ASC settings, and we believe patient experience the effect the OAS CAHPS Survey has on care delivery and quality improvement. Another commenter stated that the money spent on OAS CAHPS Survey would be less effective than spending money directly on patient care.

Response: We thank the commenters for their comments. Studies show a relationship between the clinical quality of care provided at a facility and patients' experience of care.*512 513* The OAS CAHPS Survey is specifically designed to measure of care is an important indicator of the quality of care provided at a facility. As noted above, patients are the best source for certain information about the quality of care. Additionally, we believe that the insights provided by the OAS CAHPS Survey enable objective and meaningful information to ASCs about patient experience, which will help facilities identify areas to improve patient experience and to increase communication with patients.

Comment: A commenter recommended that for the most meaningful and user-centric approach to public reporting, we should not use CCN-level reporting and instead use NPI-based reporting method because it would allow the public to directly correlate quality measure data with an individual facility.

Response: We thank the commenter for the feedback. The OAS CAHPS Survey results are collected and reported at the CCN level. However, we thank the commenter for its recommendation to report OAS CAHPS

[510] *https://oascahps.org/Survey-Materials.*

[511] *See* CAHPS Outpatient and Ambulatory Surgery Survey. Content last reviewed July 2019. Agency for Healthcare Research and Quality, Rockville, MD.

https://www.ahrq.gov/cahps/surveys-guidance/oas/index.html.

[512] Isaac, T., Zaslavsky, A.M., Cleary, P.D., and Landon, B.E. The Relationship Between Patients' Perception of Care and Measures of Hospital Quality and Safety. Health Services Research. 2010;45:1024–1040.

[513] Anhang, P. et al. Examining the Role of Patient Experience Surveys in Measuring Health Care Quality. Med Care Res Rev. 2014;71(5):552–554.

Survey-based measures data at the NPI level for patient ease and individual facility performance improvement purposes. We will consider the feasibility of requiring ASCs to collect and report OAS CAHPS Survey data at the NPI level and will put forward any proposals in future notice and comment rulemaking, but note that CCN level reporting can reduce burden for ASCs with multiple facilities under a single CCN.

After consideration of the public comments we received, we are finalizing this proposal with modification. We are finalizing voluntary reporting as part of the ASCQR Program, modified to begin in CY 2024 reporting period/CY 2026 payment determination period and mandatory reporting of the OAS CAHPS Survey-based measures, modified to begin in the CY 2025 reporting period/CY 2027 payment determination.

5. Summary of Previously and Newly Finalized ASCQR Program Quality Measure Set

a. Summary of Previously and Newly Finalized ASCQR Program Quality Measure Set for the CY 2022 Reporting Period/CY 2024 Payment Determination

Table 69 summarizes the previously and newly finalized ASCQR Program measure set for the CY 2022 reporting period/CY 2024 payment determination.

BILLING CODE 4120–01–P

TABLE 69: ASCQR Program Measure Set for the CY 2022 Reporting Period/CY 2024 Payment Determination

ASC #	NQF #	Measure Name
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel**

† NQF endorsement was removed.

* The ASC-11 measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

** We note that, if adoption finalized, an ASC/measure number will be assigned for this measure in the final rule.

b. Summary of Previously and Newly Finalized ASCQR Program Quality Measure Set for the CY 2023 Reporting Period/CY 2025 Payment Determination

Table 70 summarizes the previously and newly finalized ASCQR Program measure set for the CY 2023 reporting period/CY 2025 payment determination.

TABLE 70: ASCQR Program Measure Set for the CY 2023 Reporting Period/CY 2025 Payment Determination

ASC #	NQF #	Measure Name
ASC-1	0263†	Patient Burn
ASC-2	0266†	Patient Fall
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265†	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel

† NQF endorsement was removed.

* The ASC-11 measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

c. Summary of Previously and Newly Finalized ASCQR Program Quality Measure Set for the CY 2024 Reporting Period/CY 2026 Payment Determination and Subsequent Years

Table 71 summarizes the previously and newly finalized ASCQR Program measure set for the CY 2024 reporting period/CY 2026 payment determination and subsequent years.

TABLE 71: ASCQR Program Measure Set for the CY 2024 Reporting Period/CY 2026 Payment Determination and Subsequent Years

ASC #	NQF #	Measure Name
ASC-1	0263†	Patient Burn
ASC-2	0266†	Patient Fall
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265†	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel*

† NQF endorsement was removed.

* The ASC-11 measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

d. Summary of Previously and Newly Finalized ASCQR Program Quality Measure Set for the CY 2025 Reporting Period/CY 2027 Payment Determination and Subsequent Years

Table 72 summarizes the previously and newly finalized ASCQR Program measure set for the CY 2025 reporting period/CY 2027 payment determination and subsequent years.

TABLE 72: ASCQR Program Measure Set for the CY 2025 Reporting Period/CY 2027 Payment Determination and Subsequent Years

ASC #	NQF #	Measure Name
ASC-1	0263†	Patient Burn
ASC-2	0266†	Patient Fall
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265†	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	OAS CAHPS – About Facilities and Staff
ASC-15b	None	OAS CAHPS – Communication About Procedure
ASC-15c	None	OAS CAHPS – Preparation for Discharge and Recovery
ASC-15d	None	OAS CAHPS – Overall Rating of Facility
ASC-15e	None	OAS CAHPS – Recommendation of Facility
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel

† NQF endorsement was removed.

BILLING CODE 4120–01–C

6. ASCQR Program Measures and Topics for Future Consideration

a. Potential Adoption of Future Measures for the ASCQR Program

We continue to seek to adopt a comprehensive set of quality measures for widespread use to inform decision-making regarding care and for quality improvement efforts in the ASC setting. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083 through 86110), under the OPPS we finalized the elimination of the Inpatient Only (IPO) list over a 3-year transitional period, beginning with the removal of approximately 300 primarily musculoskeletal-related services, with the list to be completely phased out by CY 2024.[514] As discussed in section IX of the CY 2022 OPPS/ASC proposed rule (86 FR 42155), we have continued to receive stakeholder requests to reconsider the elimination of the IPO list, to reevaluate services removed from the IPO list due to safety and quality concerns, and to, at a minimum, extend the timeframe for eliminating the list. After further consideration and review of the additional feedback from stakeholders, we believe that the timeframe we adopted for removing services from the IPO list does not give us a sufficient opportunity to carefully assess whether a procedure can be removed from the IPO list while still ensuring beneficiary safety. For CY 2022, we proposed to halt the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021, we proposed to add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022.

We also proposed to reinstate the CY 2020 criteria used to add procedures to the ASC Covered Procedures List (CPL) and remove 258 of the additional 267 surgical procedures that were added to the ASC CPL beginning in CY 2021, under the CY 2021 revised criteria[515] with additional procedures being proposed for addition for CY 2022.

However, as technology and surgical techniques advance, services will continue to transition off of the IPO list, becoming payable in the outpatient hospital setting and being eligible for addition to the ASC covered procedures list in subsequent years. We recognize that there may be a need for more measures that inform decision-making regarding care and for quality improvement efforts, particularly focused on the behaviors of services that become newly eligible for payment in the ASC setting. In light of this, we sought comment on potential future adoption of measures that would allow better tracking of the quality of care for services that transition from the IPO list and may subsequently become eligible for addition to the ASC CPL.

Therefore, we invited public comment on the potential future adoption of measures for our consideration that address care quality in the ASC setting given the transition of procedures from inpatient settings to outpatient settings of care.

We received comments on these topics.

Comment: Many commenters supported the future development of measures that would allow for a comparison of outcomes across care settings, particularly as procedures transition from the inpatient only list to the outpatient and ASC settings. The commenters encouraged CMS to work with stakeholders to improve measure alignment and reporting between hospital outpatient surgery centers and ambulatory surgery centers and also identify new measures that address

[514] Centers for Medicare & Medicaid Services. (2020, December 2). CY 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System final rule (CMS–1736–FC). Retrieved from: *https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center.*

reporting challenges in the ASCQR Program.

A few commenters recommended that CMS require all accredited ASCs to submit comprehensive safety and quality data to a nonprofit organization with extensive experience in collecting and reporting ASC quality data on a public website to ensure the data is trusted and useful for purchasers and consumers. Commenters also suggested the reporting should utilize consensus-based nationally endorsed standards. The commenters stated their belief that patients and purchasers do not have access to enough information to be able to make an informed decision on care.

Response: We thank commenters for their feedback. As mentioned in section XVI.B.6.a. of the final rule with comment period, we seek to adopt a comprehensive set of quality measures for widespread use to inform decision-making regarding care and for quality improvement efforts. We will continue to work with stakeholders as we consider measures for inclusion in future rulemaking. Additionally, we agree on the importance of measure alignment. It is our goal to continue to explore ways to address measurement gaps, reduce burden and increase efficiency through measure alignment.

We also agree with commenters on the importance of submitting safety and quality data publicly to promote transparency, accountability as well as providing a means of delivering important healthcare information to consumers. Our public websites, including the Provider Data Catalog, were launched with the purpose of providing public facing quality data to help inform consumer care and to encourage healthcare facilities to make continued improvements to the quality of care provided. We will consider the feasibility of the commenters' recommendations and take them into consideration in future rulemaking.

Comment: Commenters encouraged CMS to work with stakeholders to identify measures that would be appropriate and useful across programs and to address reporting challenges before proposing to adopt new measures into the program. Several commenters suggested that CMS re-introduce measures previously proposed in the CY 2018 OPPS/ASC proposed rule including the Toxic Anterior Segment Syndrome (TASS), Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps and the Ambulatory Breast Procedure Surgical Site Infection Outcome measure. Commenters stated that these measures fill an important gap in the ASCQR Program related to addressing HAIs, colonoscopy services, and Ophthalmic devices. Commenters also noted that these measures would be appropriate for the Hospital OQR Program which would expand alignment between the Hospital OQR and ASCQR Programs and would allow consumers more opportunities to compare quality and safety across settings of care.

Additionally, one commenter recommended that CMS should improve mechanisms for comparison between hospital outpatient surgery centers and ASCs. The commenter stated that surgical procedures should produce ratings that allow for comparisons of the same procedure regardless of setting.

Response: We thank the commenters for their recommendations. We are committed to working with stakeholders to identify appropriate and useful measures across our programs and address any measurement gaps to reduce burden. Concerning the creation of ratings that would allow for comparisons of the same procedure regardless of setting, we are committed to looking for more effective ways to align our programs and will monitor this concern for future rulemaking. We thank commenters for their input on additional ASCQR Program measures and topics for future consideration and will take this feedback into account for future measure development in the ASCQR Program.

b. Potential Future Adoption and Inclusion of an ASC-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)

As described in section XVI.B.6.a. of this final rule with comment period and above, we sought comment on priorities for quality measurement in outpatient settings due to changes to the IPO procedure list (82 FR 59385 and 84 FR 61355) and the ASC CPL (84 FR 61388 and 85 FR 86146).

In the CY 2022 OPPS/ASC proposed rule (86 FR 42276 through 42277), we also requested comment on the potential future adoption of a re-specified version of a patient-reported outcome-based performance measure (PRO–PM) for two such procedures, elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA), which were removed from the IPO list effective for CY 2020 and CY 2018, respectively, and added to the ASC CPL effective for CY 2021 and CY 2020, respectively. We recently solicited public comment on the potential future inclusion of a Hospital-level THA/TKA PRO–PM (NQF #3559) in the FY 2022 IPPS/LTCH PPS proposed rule for the inpatient hospital setting (86 FR 25589) and responded to public comments received in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45408). This measure reports the hospital-level risk-standardized improvement rate (RSIR) in patient-reported outcomes (PROs) following elective primary THA/TKA for Medicare fee-for-service (FFS) beneficiaries aged 65 years and older. Substantial clinical improvement is measured by achieving a pre-defined improvement in score on one of the two validated joint-specific PRO instruments measuring hip or knee pain and functioning: (1) The Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) for completion by THA recipients; and (2) the Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients. Improvement is measured from the preoperative assessment (data collected 90 to 0 days before surgery) to the postoperative assessment (data collected 300 to 425 days following surgery). Improvement scores are risk adjusted to account for differences in patient case mix. Potential non-response bias in measure scores due to the voluntary nature of PROs is incorporated in the measure calculation with stabilized inverse probability weighting based on likelihood of response.

Given the recent changes in the ASC CPL, we expect that THA and TKA procedures will increasingly be performed in ASCs and that the volume of these procedures on Medicare beneficiaries 65 and older will also increase in ASCs in future years.

We recognize that potential future adoption and implementation of a re-specified version of the THA/TKA PRO–PM in the ASCQR Program would require sufficient numbers of procedures for each measured ASC to ensure a reliable measure score. As only a subset of ASCs performs orthopedic procedures, the measure would likely apply to a minority of ASCs. Additionally, implementing a THA/TKA PRO–PM would require providers to successfully collect pre- and post-operative PRO data for each procedure. Specifically, the inpatient THA/TKA PRO–PM discussed in the FY 2022 IPPS/LTCH PPS proposed rule requires a minimum of 25 cases with completed pre- and post-operative PRO data per hospital to ensure a reliable facility-level score. For more details on the inpatient THA/TKA PRO–PM, we refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25589), the FY 2022 IPPS/LTCH PPS final rule (86 FR

45408) and the PROs Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

We will continue to monitor the number of THA and TKA procedures in ASCs and when we believe there is a sufficient number of such procedures performed in ASCs to reliably measure a meaningful number of facilities, we may consider expanding the PRO–PM to this setting. We also note that, as finalized in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59455 through 59463), the ASCQR Program currently includes a Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures (ASC–17) measure using claims data which provides facilities with important information on patient outcomes for Medicare FFS beneficiaries following orthopedic surgery at ASCs and this measure includes THA and TKA procedures. The ASC–17 measure calculates a facility-specific risk-standardized hospital visit ratio within 7 days of an orthopedic procedure performed at an ASC and has as outcomes of interest unplanned hospital admissions, emergency department (ED) visits, and observation stays, thereby, providing valuable quality information for these procedures as they expand into the ASC setting.

As described in our Meaningful Measures 2.0 Framework, we aim to promote better collection and integration of patients' voices by developing PRO measures as an additional tool for measuring and improving quality. Given the unique challenges and opportunities for PRO–PMs for THA and TKA procedures in the ASC setting, we invited public comment on the potential future adoption of a respecified version of PRO measures for elective THA/TKA PRO–PM for the ASCQR Program. Specifically, we invited public comment on the following:

- Input on the mechanism of PRO data collection and submission, including anticipated barriers and solutions to data collection and submission.
- Usefulness of having an aligned set of PRO–PMs across settings where elective THA/TKAs are performed, that is, hospital inpatient setting, hospital outpatient departments, and ASCs for patients, providers, and other stakeholders. Specifically, usefulness and considerations for a healthcare system that performs inpatient and/or outpatient and ASC elective THA/TKAs.
- Considerations unique to THA/TKAs performed in the ASC setting such as the volume of procedures performed or the measure cohort, outcome, or risk adjustment approach.

We received comments on these topics.

Comment: Several commenters expressed support for the potential future adoption and inclusion of an ASC-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA). Commenters noted that as procedures shift to the outpatient setting, it is important for quality programs to reflect the settings in which beneficiaries receive surgical care and agreed that PROs are the best available means for a patient-centered measurement of functional status improvement. Commenters expressed support for this measure across multiple settings, including hospitals, outpatient departments, and ambulatory surgical centers. Additionally, a few commenters expressed support for the patient-reported outcome surveys used to collect preoperative and postoperative data. The Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) and the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) are widely used across the country and are lower burden compared to the HOOS and KOOS. Commenters also supported use of either the Patient-Reported Outcomes Measurement Information System (PROMIS)-Global or the Veterans RAND 12-Item Health Survey (VR–12) for risk adjustment and felt that measure development was responsive to stakeholder feedback.

Response: We thank the commenters for their support and will consider these comments for future policy development.

Comment: A few commenters expressed concern about data collection and reporting thresholds. Commenters encouraged CMS to explore ways to reduce the burden of collecting patient-reported outcomes data and support hospitals in their efforts to increase responsiveness. Some commenters expressed concern over the increasing threshold for submitting data, noting that the threshold within the Comprehensive Care for Joint Replacement (CJR) model incrementally increased over time and fewer hospitals have been able to meet the thresholds. Commenters asked CMS to explain the rationale behind the chosen thresholds and consider whether a lower rate of response is sufficient for measuring performance. One commenter recommended phased implementation of the measure to allow facilities time to coordinate collection and reporting of PRO data. They recommended a two-year voluntary reporting period to allow facilities who were not part of the CJR model to build up infrastructure to collect data and further research to determine exemption criteria for low volume facilities. One commenter also expressed concern about patient burden, noting that patient response rates to various surveys across the continuum of care are dropping, and increasing the number of surveys may result in fewer completed surveys overall.

Response: We thank the commenters for their feedback and would like to provide more explanation regarding the reporting thresholds as described in prior rules. Through the CJR final rules, we finalized a data submission requirement that strategically increased with each performance year. To be successful, a hospital needed to submit PRO data for 50 percent or 50 eligible procedures in the first year of the model. By performance year 8, hospitals will need to submit PRO data for 90 percent or 500 eligible procedures to be successful. The incremental increase over a set period of time allows hospitals to gradually build up their infrastructure and processes for collecting and storing data. Future proposals for implementation and reporting of this measure will be announced through notice and comment rulemaking. While patient-reported outcome-based performance measures require providers to integrate data collection into clinical workflows, this integration provides opportunity for PROs to inform clinical decision making and benefit patients by engaging them in discussions about potential outcomes. We do not expect this PRO–PM to contribute to survey fatigue or to negatively impact other PRO–PMs. The Patient-Reported Outcome Measure (PROM) instruments that are used to calculate preoperative and postoperative data scores for this THA/TKA PRO–PM were carefully selected, with extensive stakeholder input, to be low burden for patients and to capture information clinicians deemed essential to understanding response to THA/TKA.

Comment: A few commenters called for robust risk adjustment for this measure. They noted patients who receive these procedures in the inpatient setting will tend to be sicker and more complex compared to patients who receive these procedures in the outpatient or ASC setting. Commenters encouraged CMS to take the differences

in patient complexity into account when developing a risk adjustment strategy and to do so in a way that minimizes lag between the procedure and reporting. Commenters also encouraged CMS to consider incorporating sociodemographic factors, such as dual eligibility status and preferred language, and stratifying results by proportions of dual-eligible patients similar to the approach now used by the CMS Hospital Readmission Reduction Program.

Response: We thank the commenters for their insights on the differences in patient complexity across different care settings and the impact it may have on risk adjustment. We will continue to take this into consideration if we move forward with re-specifying this measure for use in ASCs. With respect to sociodemographic factors, we would like to clarify the risk adjustment approach. For the development of the hospital-level measure, we assessed the impact of dual eligibility, the Agency for Health Research and Quality (AHRQ) socioeconomic status (SES) Index (socioeconomic status), and non-white race. The addition of each of these three social risk variables provided no statistically significant change to the risk model performance, variable coefficients, or the model outcome. As such, these variables were not included in the hospital risk model. These social risk variables were, however, statistically significantly associated with response to PRO surveys—whether patient-reported outcomes were obtained for patients undergoing primary elective THA/TKA—and so were included in the calculation of stabilized inverse probability weights used to account for potential response-bias. These variables, along with other sociodemographic variables that may become available over time, will be reassessed as part of the respecification process if CMS proceeds with developing a version of the measure for the ASC setting as part of CMS' commitment to addressing improving health equity.

Comment: A few commenters recommended use of the American Joint Replacement Registry (AJRR) for future implementation of this measure citing that participation in the AJRR is a requirement for certification as a center of excellence by The Joint Commission. The commenters felt that using the AJRR would allow facilities to pool their resources for lowest costs. They also noted that as the AJRR incorporates Medicare Administrative Data for populating the database, its use would allow for robust risk adjustment, improved research, and independent reporting for participating facilities to normalize quality. The AJRR is widely used by providers in the United States and implementing the measure through the AJRR will minimize duplication of reporting efforts. Commenters felt this approach would be faster, more efficient, and would incentivize use of Qualified Clinical Data Registries (QCDRs).

Response: We appreciate commenters' recommendations regarding the AJRR and we will consider the feasibility and appropriateness of using this registry for future implementation, if we proceed with development of a THA/TKA PRO–PM in ASCs. We agree that leveraging existing resources, such as registries, will help decrease patient and provider data collection burden.

Comment: A few commenters provided feedback on future implementation of this measure. One commenter recommended a benchmark approach to facility measure scores, where CMS would evaluate success by establishing a benchmark percentage of THA/TKA procedures reaching a significant clinical improvement, rather than requiring providers to compete for percentile rankings of success rates across tightly bunched score rates. Another commenter recommended that CMS consider incentivized, phased implementation that would allow facilities to build up their processes and infrastructure to collect and report on patient-reported outcomes data. They also encouraged CMS to reevaluate the minimum number of cases that would trigger reporting as low volume can lead to wider variances in outcomes for smaller volume hospitals.

Response: We appreciate commenters' recommendations regarding future implementation of the measure. With regards to facilities' ability to meet the reporting threshold, we agree that there must be a sufficient number of procedures in these settings to reliably measure a meaningful number of facilities, and we anticipate an increase in the number of THA/TKA procedures performed in ASCs in future years. We will continue to take this into consideration if we move forward with respecifying the measure for use in ASCs. Any future proposals to implement the measure will be announced through notice and comment rulemaking.

Comment: A few commenters did not support potential future adoption and inclusion of an ASC-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary THA/TKA. Commenters noted that ASC regulations limit the scope of ASC services and the timeframe during which ASCs are permitted to be involved in patient care. As such, ASCs are limited in their preoperative, intraoperative, and postoperative services.

Response: We acknowledge the commenter's concern and will consider the impact of regulatory requirements on any future measurement, but we believe it is important to monitor quality in all settings where these procedures are performed. As performance of THAs and TKAs shift into the outpatient and ASC settings, it is important for quality measurement programs to adapt to the changing care settings.

Comment: One commenter recommended development of a surgical site infection measure following THA and TKA.

Response: We thank the commenter for their suggestion. Surgical site bleeding and surgical site complications during the index admission or a subsequent inpatient admission within 30 days from the start of the index admission are captured in the hospital-level risk-standardized complication rates (RSCRs) following an elective primary THA and/or TKA measure in the Hospital Value-Based Purchasing Program. Hospital admissions within seven days of the surgery are captured in the Hospital Visits after Hospital Outpatient Surgery (OP–36) measure for procedures performed in the outpatient setting. Any future measure development or respecification proposals for ASCs will be announced through notice and comment rulemaking. We thank commenters for their input on the potential future adoption of an ASC-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) and will take this input into account for future measure development in the ASCQR Program.

c. Potential Future Efforts To Address Health Equity in the ASCQR Program

(1) Background

Significant and persistent inequities in health care outcomes exist in the U.S. Belonging to racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; and being near or below the poverty level, are often associated with worse health

[516] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

outcomes.[516] [517] [518] [519] [520] [521] [522] [523] Such disparities in health outcomes are the result of number of factors, but importantly for CMS programs, although not the sole determinant, negative experiences, poor access, and provision of lower quality health care contribute to health disparities. For instance, numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[524] [525] [526] [527] [528] [529] Readmission rates for common conditions in the Hospital Readmissions Reduction Program (HRRP) are higher for Black Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with Congestive Heart Failure and Acute Myocardial Infarction.[530] [531] [532] [533] [534] Studies have also shown that African Americans are significantly more likely than White Americans to die prematurely from heart disease and stroke.[535] The COVID–19 pandemic has further highlighted many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among Black, Latino, and Indigenous and Native American persons relative to White persons.[536] [537] As noted by the CDC, ''long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID–19.'' [538] One important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across our programs and policies.

We are committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[539] In the CY 2022 OPPS/ASC proposed rule (86 FR 42277 through 42279), we used a definition of equity established in Executive Order 13985, issued on January 25, 2021, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; LGBTQ+ persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [540] We noted that this definition was recently established and provides a useful, common definition for equity across different areas of government, though numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Innovation Network-Quality Improvement Organizations (QIN–QIOs); Federal, state, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity.[541]

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45349) which summarizes our existing initiatives aimed at closing the equity gap in outcomes for Medicare beneficiaries. We also refer readers to section XV.B.7.c.(1). of the CY 2022

[517] Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013;346.

[518] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014;371(24):2298–2308.

[519] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[520] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf*.

[521] U.S. Department of Health and Human Services Office of Minority Health. 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities, FY 2020. Available at: *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf*.

[522] Heslin KC, Hall JE. Sexual Orientation Disparities in Risk Factors for Adverse COVID–19–Related Outcomes, by Race/Ethnicity — Behavioral Risk Factor Surveillance System, United States, 2017–2019. MMWR Morb Mortal Wkly Rep 2021;70:149–154. DOI: *http://dx.doi.org/10.15585/mmwr.mm7005a1*. Available at: *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm*.

[523] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv*. 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[524] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[525] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf*.

[526] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec;73(12):2107–15.

[527] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[528] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[529] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[530] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. Am Heart J. Aug 2011;162(2):254–261 e253.

[531] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

[532] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf*.

[533] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. Chronic obstructive pulmonary disease readmissions at minority-serving institutions. Ann Am Thorac Soc. Dec 2013;10(6):680–684.

[534] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[535] HHS. Heart disease and African Americans. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19*.

[536] CMS. Preliminary Medicare COVID–19 Data Snapshot. (April 16, 2021). Available at: *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf*.

[537] Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/*.

[538] CDC. Health Equity Considerations & Racial & Ethnic Minority Groups. (April 19, 2021). Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html*.

[539] CMS. CMS Quality Strategy. (2016). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf*.

[540] Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. 86 FR 7009 (Jan. 20, 2021). Available at: *https://www.federalregister.gov/documents/2021/01/25/2021–01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*.

[541] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf*.

OPPS/ASC proposed rule (86 FR 42253) which describes the policy and statute which have informed the creation of the CMS Disparity Methods to provide confidential stratified results for measures in the hospital inpatient setting using dual eligibility as a proxy for social risk. Our efforts to stratify outcome measures by dual eligibility are supported by national recommendations from the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academies of Sciences, Engineering, and Medicine, which identified dual eligibility, an indicator of social risk, as a powerful predictor of poor health outcomes among the social risk factors that were tested.[542] [543]

To date, we have not expanded disparities reporting to the ASC setting. Internally testing the two disparities methods (Within- and Across-Hospital Disparity Methods) on ASCQR Program quality measures calculated using Medicare FFS claims revealed several unique challenges to measuring disparities for dually eligible individuals in the ASC setting, principally, relatively low volumes of dual eligible patients in many facilities, and large diversity in the types and patient mix between ASCs as these facilities tend to specialize. In our initial analysis, few facilities met the minimum sample size required to yield technically feasible, adequately representative, and statistically reliable disparity results. We are considering social risk factors, including neighborhood-level social determinants of health, such as the poverty, education, and housing quality, which can adversely influence health outcomes, contributing to health inequities, in order to report more information regarding equity gaps in the care provided in the ASC setting. There are several different approaches for quantifying the health impacts of adverse neighborhood level socioeconomic factors. One approach is the Agency for Healthcare Research and Quality (AHRQ) neighborhood Socioeconomic Status (SES) Index, which uses information from the U.S. Census at the census block-group level to estimate the range of socioeconomic status in the beneficiary's neighborhood.[544] In the CY 2022 OPPS/ASC proposed rule (86 FR 42279), we sought comment on and were interested in learning more about the potential for measuring disparities in care provided in this setting.

(2) Solicitation of Public Comments

In the CY 2022 OPPS/ASC proposed rule (86 FR 42279), we sought comment on the possibility of providing equity reporting in the ASCQR Program in a way that maximally supports facilities in improving the quality of care for all Medicare beneficiaries, regardless of their socioeconomic status or other risk factors. We were particularly interested in learning about measurement approaches or social risk factors which may permit illuminating social-based disparities in facilities which have relatively few individuals who possess social risk factors. Specifically, we invited public comment on the following:

- Ways to address the unique challenges of measuring disparities in the ASC setting, such as small sample sizes, ASC specialization, and the relatively smaller proportion of patients with social risk factors.
- The utility of neighborhood-level socioeconomic factors toward measuring disparities in quality-of-care outcomes for ASCs.
- Ways social risk factors influence the access to care, quality of care and outcomes for ASC patients in general or for specific ASC services.

We received comments on these topics.

Comment: Many commenters expressed support for CMS' commitment to address health disparities and closing the health equity gap. Some commenters specifically supported collection and reporting of stratified disparities information in the ASC setting and recommended specific data that CMS should collect. One commenter expressed strong support for data collection and measurement by characteristics including race, ethnicity, sex, sexual orientation, gender identity, language preference, tribal membership, and disability status. This commenter urged CMS to avoid using indirect estimation methods for race and ethnicity data, and instead establish a timeframe for meeting specific direct data collection goals, including data completeness and accuracy requirements.

Another commenter asserted that emerging evidence suggests that healthcare disparities may be rooted in lived experiences, and recommended CMS include questions that specifically address the experiences of racialized minorities within the healthcare system, such as trust of the healthcare system and providers, experiences of microaggression, and perceived discrimination or injustices. The commenter also recommended CMS accommodate the literacy needs and linguistic barriers of patients during these data collection efforts. Another commenter recommended CMS and providers collect data on nutritional status and specifically malnutrition to understand and improve health equity, since malnutrition is a risk factor for worse outcomes after surgery or trauma. An additional commenter supported stratification initially by race and ethnicity, but suggested future expansion to primary language, geographic location, socioeconomic status, gender identity, sexual orientation, age, and ability status.

An additional commenter described working on a Health Equity Report Card tool to reduce racial disparities in other care settings. Another commenter described developing a social determinants of health (SDOH) report based on the U.S. Department of Health and Human Services (HHS) Health People 2030 framework that recommends developing a standard set of SDOH definitions, utilizing community-based organizations, and building a national clearinghouse of program information and best practices, all aimed at reducing health disparities. This commenter also recommended CMS consider the three general paths that have been identified by the American Hospital Association in vulnerable communities including screening patients for social needs, offering navigation services to help patients access community services, and partnering with community stakeholders to align with local needs.

Response: We appreciate the feedback provided by the commenters regarding approaches for incorporating other demographic characteristics and social risk factors into analyses that address and advance health equity. We will continue to take all concerns, comments, and suggestions into account in our future policies.

We are also sensitive to the concerns raised by stakeholders about indirect estimation. As referenced in the

[542] Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs*.

[543] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

[544] Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

proposed rule (86 FR 42018) and summarized in the 2022 IPPS final rule (86 FR 25070), the Medicare program does not directly collect information from beneficiaries on race and ethnicity, instead relying on data collected by the Social Security Administration. A number of barriers contribute to this information being insufficiently accurate to examine hospital-level disparities. For example, prior to 1980, only three categories (White, Black, and Other) were available for individuals to self-report race, and respondents were not able to indicate Asian, American Indian/Alaska Native, Hispanic, or Pacific Islander identities. As a result of these constrained response options, many current beneficiaries may not have had the opportunity to accurately self-report their race and ethnicity. Although we have undertaken significant efforts to update incorrect race and ethnicity information many inaccuracies remain limiting our ability to measure disparities.

In recent years we have sponsored the development of two indirect estimation algorithms, both intended to correct and improve administrative information on race and ethnicity. Indirect estimation methods such as these can generally be used in two different ways: (a) To estimate race/ethnicity in the absence of self-reported data; or (b) to improve administrative data in which beneficiaries provided a self-report of race/ethnicity but were not permitted a full set of response options (post-1980). While there is evidence supporting the validity of both approaches, accuracy and performance is particularly high in situation (b), where indirect estimation allows the administrative variables to better match the responses people would give when permitted a full set of response options. The approach for indirect estimation we intend to apply is situation (b), which uses an algorithm to augment existing data to allow a constrained administrative self-reported variable to better match what Medicare beneficiaries themselves may have chosen when given a comprehensive set of response options on race and ethnicity.

The Medicare Bayesian Improved Surname Geocoding Version 2.1 (MBISG 2.1) uses the original beneficiary self-report, but uses additional information supplied by Medicare beneficiaries and information about neighborhood composition, to make this variable better match what Medicare beneficiaries themselves self-report when given a full set of response options. With respect to Asian and Pacific Islander, Black, Hispanic, and White Medicare beneficiaries, the improved version of the administrative variable has 96–99% concordance with what Medicare beneficiaries themselves report when allowed a full set of response options, matching much better than the original self-reported variable in which most Medicare beneficiaries were not allowed to indicate Asian, American Indian/Alaska Native, Hispanic, or Pacific Islander identities. The MBISG 2.1 also offers distinct advantages because it generates probabilities of identification in each racial and ethnic group for each beneficiary, rather than assigning a single identification.

The MBISG 2.1 incorporates multiple sources of information to develop racial and ethnic probabilities. In addition to the information on race and ethnicity which that person reported to the SSA, the model also considers the person's first and last name, the composition of the census block group where they live, and other demographic information that Medicare beneficiary shared. Through such a holistic approach, the MBISG 2.1 can make accurate comparisons between groups of Medicare beneficiaries regarding the quality of care received, including people whose surnames are common among several racial and ethnic groups, and people who changed their surnames upon marriage. The MBISG 2.1 is also designed to consider those who identify as Multiracial and allows measurement in Census categories that distinguish those who chose single or multiple racial identity, as well as considering endorsement of Hispanic ethnicity separately. Notably, we only intend to use the MBISG 2.1 to make inferences about aggregated groups at the hospital level, and do not intend to use it to make inferences about any single individual, validation studies indicate that these aggregate estimates further improve upon the higher predictive accuracy of the model.

We believe that use of statistical imputation models, such as the MBISG 2.1 would permit us to provide more accurate, less biased information on disparities in hospital outcomes when reported confidentially. We plan to report results confidentially to facilities in Spring 2022 where results are technically feasible, meaningful, and statistically reliable. Any potential future proposal to publicly display the disparity results would be made through future rulemaking. We are sensitive to the concerns raised by stakeholders and will continue to evaluate the validity of the readmission measures when stratified by indirect estimation during the confidential reporting period.

Comment: Several commenters noted the difficulty of collecting data related to health disparities and reliable patient demographic information and recommended CMS support facilities with data collection efforts. One commenter noted provider time constraints as an impediment to collecting demographic and social risk factor data and recommended CMS considering developing and reimbursing for billable encounters related to social determinants of health screening. A few commenters also recommended CMS standardize collection and reporting of social risk factor data. Commenters recommended using screening tools such as the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) tool or the Accountable Health Communities Health-Related Social Needs Screening Tool developed by CMS. Another commenter asserted that without standardized tools, providers lack the necessary information to uniformly assess and identify potential social risk factors among patients. Several commenters urged CMS to develop information technology standards and consistent guidance across programs for the capture, use, and exchange of relevant data such as the use of electronic health records and FHIR standards. One commenter noted that facilities have had difficulty collecting demographic information for other quality measurement programs and should not be penalized for submission of data that is inaccurate or incomplete for reasons beyond their control.

Response: We appreciate the feedback provided by the commenters regarding standardization of demographic data collection to additional social risk factors for the purposes of illuminating health inequities. We will continue to take all concerns, comments, and suggestions into account in our future policies.

Comment: Several commenters provided helpful insights into the unique challenges of measuring disparities in ASCs and potential ways to address these challenges. With regards to small sample size, several commenters recommended facility-level instead of measure-specific equity measurement, such as utilizing outcome measures that are applicable across multiple procedures with adjustment by procedure type or aggregating the ASCQR measures for each facility. A commenter also recommended addressing upstream access challenges that can lead to the smaller proportion of patients with social risk factors receiving care in ASCs, such as by developing and utilizing access measures. The commenter also suggested CMS consider developing and

implementing measures that directly assess health equity, such as structural measures that assess an organization's commitment to equity, collecting demographic data, and ensuring training on best practices; and measuring areas such as access, community partnerships, and patient experiences centered on identifying discrimination and structural racism. A commenter requested CMS support facilities in accessing and collecting socioeconomic data in the future.

Response: We appreciate the feedback provided by the commenters regarding the unique challenges of measuring disparities in ASCs. We will take commenters' feedback into consideration in future policy development.

Comment: A few commenters expressed support for incorporating neighborhood-level socioeconomic factors into methods for measuring disparities, especially when there are limitations in sample size or availability of more granular data. One commenter asserted that neighborhood-level socioeconomic factors can tell important information about the conditions in which people live, work, and play, and understanding them is vital to improving health outcomes. The commenter noted that since such data is less accurate than patient-level data, they recommended that CMS initially use results stratified by neighborhood-level factors for confidential reporting. If CMS chooses to publicly report results stratified by neighborhood-level factors, the commenter recommended we demonstrate the statistical soundness of the results prior to public reporting. Similarly, another commenter expressed concern that the approach of using neighborhood-level socioeconomic factors is susceptible to an ecologic fallacy which could vary greatly across different regions. One commenter recommended that standardizing CMS' SDOH data collection and measurement initiatives will not be enough—they must also incorporate tools that help clinicians connect patients with the community resources they need in order to improve outcomes.

Response: We appreciate the feedback provided by the commenters regarding the potential incorporation of neighborhood-level socioeconomic factors into methods for measuring disparities in ASCs, and for additional measures of equity in this setting. We will take commenters' feedback into consideration in future policy development.

Comment: Several commenters discussed the incorporation of existing codes into risk adjustment. One commenter recommended CMS evaluate the use of existing SDOH billing codes and the International Classification of Diseases, 10th Revision (ICD–10) Z codes which identify non-medical factors that may influence a patient's health status and recommended CMS consider developing additional codes for social needs care across payers to promote screening and referrals for social services. Another commenter recommended incorporating social risk adjustment into traditional hierarchical condition categories (HCCs)/clinical risk adjustment models. However, another commenter provided an example of how incorporating social risk factors such as dual eligibility, the AHRQ SES index, or non-white race into a hospital measure risk model didn't provide evidence of significant differences in outcomes and encouraged CMS to test such factors in current or future ASCQR Program measures.

Response: We appreciate the feedback provided by the commenters regarding risk adjustment for social risk and demographic variables in ASC quality measurement. We will take commenters' feedback into consideration in future policy development.

Comment: While supportive of collecting and utilizing demographic and SDOH data to measure and improve health equity, several commenters expressed concerns about protecting patient privacy. One of these commenters recommended CMS increase beneficiary education on the sharing of their sensitive health information with their providers. Another of these commenters asked that CMS answer privacy questions such as where the data will be kept, what happens if a patient declines to answer these questions for providers and/or do not wish to share the data with CMS? This commenter also questioned whether utilizing EHRs to data-mine patient data would comply with HIPPA and the OIG's provisions regarding interoperability and information blocking.

Response: We are very sensitive to data privacy, and of patient education and empowerment. We appreciate the feedback provided by the commenters on these topics, and we will take commenters' feedback into consideration in future policy development.

Comment: Several commenters noted that social factors broadly influence access to care at ASCs, including for example, reimbursement differences between Medicaid and other forms of insurance, federal and state policies regarding ASCs, access to specialty care, and transportation barriers. One commenter encouraged measurement of access to care barriers, community factors, and patient experiences centered on identifying discrimination and structural racism could help address barriers to receiving care in an ASC.

Response: We appreciate the feedback provided by the commenters on the unique challenges of providing care to patients with social risk factors at ASCs. We will take commenters' feedback into consideration in future policy development.

We thank commenters for their input on the potential future efforts to address health equity in the ASCQR Program and will take this input into account for future measure development in the ASCQR Program.

d. Future Development and Inclusion of a Pain Management Measure

Chronic pain is linked to a number of adverse physical and mental conditions [545] [546] [547] [548] and contributes to increased health care costs.[549] An estimated 20.4 percent (50 million) of U.S. adults have chronic pain.[550] As patients with acute and chronic pain continue to face challenges in obtaining adequate care,[551] Congress has advanced policies to improve the treatment of pain and substance use disorders. The Comprehensive Addiction and Recovery Act of 2016

[545] Institute of Medicine (US) Committee on Pain, Disability, and Chronic Illness Behavior; Osterweis M, Kleinman A, Mechanic D, editors. Washington (DC): National Academies Press (US); 1987. Available at: *https://www.ncbi.nlm.nih.gov/books/NBK219250/*.

[546] Hooten WM. Chronic Pain and mental Health Disorders: Shared Neural Mechanisms, Epidemiology, and Treatment. (2016). May Clinic Proceedings. Available at: *https://www.mayoclinicproceedings.org/article/S0025-6196(16)30182-3/fulltext*.

[547] De Heer EW, Gerrits MMJG, Beekman ATF, Dekker J, van Marwijk HWJ, de Waal MWM, Spinhoven P, Penninx BWJH, van der Feltz-Cornelis CM. (2014). The Association of Depression and Anxiety with Pain: A Study for NESDA. PLOS ONE 9(12): e115077. *https://doi.org/10.1371/journal.pone.0115077*.

[548] Rayner L, Hotopf M, Petkova H, Matcham F, Simpson A, and McCracken LM. (2016). Depression in patients with chronic pain attending a specialized pain treatment centre: prevalence and impact on health care costs. Pain; 157(7): 1472–1479. doi: 10.1097/j.pain.0000000000000542.

[549] Gaskin DJ and Richard P. (2012). The Economic Costs of Pain in the United States. The Journal of Pain; 13(8): 715–724. Available at: *https://www.jpain.org/article/S1526-5900(12)00559-7/pdf#:~:text=The%20additional%20health%20care%20costs,from%20%24299%20to%20%24335%20billion*.

[550] Dahlhamer J, Lucas J, Zelaya, C, et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016. MMWR Morb Mortal Wkly Rep 2018;67:1001–1006. DOI: *http://dx.doi.org/10.15585/mmwr.mm6736a2*.

[551] *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf*.

(CARA) (Pub. L. 114–198), the 21st Century Cures Act (Pub. L. 114–225), and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271) outline evidence-based national strategies and prevention toward reducing opioid dependence. In conjunction with the opioid epidemic efforts, the SUPPORT Act also provides guidelines for providers to be prepared to discuss pain management risks and options with patients, including providing referrals to a pain management specialist.[552] As a result of the opioid epidemic and as pain management procedures become more advanced, pain management practices and surgery centers have become increasingly viewed as feasible for the initial treatment of pain as well as for the expansion of non-opioid treatments for pain management.[553] Based on a growing body of evidence on the risks of opioid misuse, we have developed a strategy to impact the national opioid misuse epidemic by combating nonmedical use of prescription opioids, opioid use disorder, and overdose through the promotion of safe and appropriate opioid utilization, improved access to treatment for opioid use disorders, and evidence-based practices for acute and chronic pain management.[554]

With advances in techniques and growing recognition by providers that pain is a treatable condition, pain management services have seen rapid growth as a form of early intervention [555] and more such procedures are being performed in ASCs.[556] ASCs specializing in pain management services are also growing as a share of overall ASCs.[557] The most common multispecialty ASCs that focused on two specialties in 2017 were those specializing in pain management and either neurology or orthopedic services.[558]

We internally analyzed CY 2019 and CY 2020 Medicare FFS claims data using the methodology previously adopted for the ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures measure (76 FR 74507 through 74509), which identifies procedure categories for the top 100 current procedural terminology (CPT®) codes reimbursed (we refer readers to Table 73). In our analyses of the Medicare FFS claims data from CY 2019 and CY 2020, we found that overall, the number of procedures declined 22 percent, likely reflecting conditions imposed by the COVID–19 PHE. The rank ordering of the types of procedures performed remained constant for the most part with pain management procedures (contained in the Nervous System category) being the third most commonly performed procedure category with 22.3 percent and 22.6 percent in CY 2019 and CY 2020, respectively.

TABLE 73: ASC Procedures from Medicare FFS Claims for CY 2019 and CY 2020 Based on CPT Codes

CY 2019				CY 2020				% Decline CY 2019 to CY 2020
Procedure Category	# of CPTs	# of Procedures	% of Total Procedures	Procedure Category	# of CPTs	# of Procedures	% of Total Procedures	
Gastrointestinal	15	1,895,911	32.9%	Gastrointestinal	15	1,479,220	32.5%	22.0%
Eye	19	1,864,585	32.3%	Eye	19	1,469,128	32.2%	21.2%
Nervous System	22	1,287,131	22.3%	Nervous System	22	996,813	21.9%	22.6%
Musculoskeletal	14	265,967	4.6%	Musculoskeletal	15	233,791	5.1%	12.1%
Genitourinary	8	169,470	2.9%	Genitourinary	8	143,894	3.2%	15.1%
Skin	8	119,329	2.1%	Skin	9	95,001	2.1%	20.4%
Imaging	7	89,075	1.5%	Imaging	6	66,939	1.5%	24.9%
Dialysis-related	3	51,102	0.9%	Dialysis-related	3	54,749	1.2%	-7.1%
Respiratory	3	20,330	0.4%	Respiratory	2	11,562	0.3%	43.1%
Anesthesia	1	6,635	0.1%	Anesthesia	1	6,062	0.1%	NA
Total	100	5,769,535	100.0%		100	4,557,159	100.0%	22.0%

Thus, we see pain management surgical procedures as a significant portion of procedures performed in the ASC setting and that an applicable measure would provide important quality of care information for a specialty not included in the current ASCQR Program measure set.

We received comments on these topics.

Comment: Many commenters supported this request for comment to

[552] H.R.6—SUPPORT for Patients and Communities Act. Available at: *https://www.congress.gov/bill/115th-congress/house-bill/6/text.*

[553] MedPac. Report to the Congress: Medicare Payment Policy, Chapter 16: Opioids and alternatives in hospital settings—Payments, incentives, and Medicare data. Available at: *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch16_sec.pdf?sfvrsn=0.*

[554] CMS Opioid Misuse Strategy 2016. Available at: *https://www.cms.gov/outreach-and-education/outreach/partnerships/downloads/cms-opioid-misuse-strategy-2016.pdf.*

[555] Manchikanti, L, Parr A, Singh V, Fellows B. Ambulatory Surgery Centers and Interventional Techniques: A Look at Long-Term Survival. Pain Physician 2011; 14: E177–215. Available at: *https://www.painphysicianjournal.com/current/pdf?article=MTQ1MQ%3D%3D&journal=60.*

[556] Manchikanti, L, Parr A, Singh V, Fellows B. Ambulatory Surgery Centers and Interventional Techniques: A Look at Long-Term Survival. Pain Physician 2011; 14: E177–215. Available at: *https://www.painphysicianjournal.com/current/pdf?article=MTQ1MQ%3D%3D&journal=60.*

[557] MedPac. Report to the Congress: Medicare Payment Policy, Chapter 5: Ambulatory Surgical Center Services. Available at: *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf?sfvrsn=0.*

[558] Report to the Congress: Medicare Payment Policy, Ambulatory Surgical Center Services. March 2019. Available at: *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf?sfvrsn=0.*

assess the future inclusion of a pain management surgical procedures measure. The commenters encouraged CMS to continue to implement policies that will incentivize and promote nonopioid, nonpharmacological treatment of pain and innovative pain management therapies. They also encouraged CMS to work with pain specialty societies, CRNAs and ASC industry representatives on the development of future pain management specialty measures.

A few commenters offered additional pain management measurement recommendations including: tracking health equity issues in pain management, and adding patient reported outcome performance measures (PRO–PM) to include service delivery. One commenter also recommend that PRO–PM measures are the best measurement type to gauge a patient's status prior to health service intervention. Lastly, one commenter recommended that CMS facilitate an open forum to discuss ASCQR measures.

Response: We thank the commenters for their suggestions. As discussed in the RFC on THA/TKA PRO–PM measure, we are considering the future implementation of PRO–PM measures across the quality reporting programs. We thank commenters for their input on the potential future development and adoption of a pain management measure and will take the feedback received into account for future measure development in the ASCQR Program.

7. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CYs 2012, 2013, 2014, 2015, and 2016 OPPS/ASC final rules with comment period (76 FR 74513 through 74514; 77 FR 68496 through 68497; 78 FR 75131; 79 FR 66981; and 80 FR 70531, respectively) for detailed discussion of our policies regarding the maintenance of technical specifications for the ASCQR Program which are codified at 42 CFR 416.325. We did not propose any changes to these policies in the proposed rule.

We also refer readers to section XIV. of the CY 2022 OPPS/ASC proposed rule (86 FR 42232 through 42237) where we requested information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the Fast Healthcare Interoperability Resources (FHIR) standard (as described in that section).

8. Public Reporting of ASCQR Program Data

We refer readers to the CYs 2012, 2016, 2017, and 2018 OPPS/ASC final rules with comment period (76 FR 74514 through 74515; 80 FR 70531 through 70533; 81 FR 79819 through 79820; and 82 FR 59455 through 59470, respectively) for detailed discussion of our policies regarding the public reporting of ASCQR Program data, which are codified at 42 CFR 416.315 (80 FR 70533). We did not propose any changes to these policies in the proposed rule.

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Administrator

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75132 through 75133) for a detailed discussion of the QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533), we codified the administrative requirements regarding the maintenance of a QualityNet account (now referred to as the HQR system HCQIS Access Roles and Profiles (HARP) ID) and security administrator for the ASCQR Program at § 416.310(c)(1)(i). In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86189), we finalized the use of the term ''security official'' instead of ''security administrator'' to denote the exercise of authority invested in the role. The term ''security official'' refers to ''the individual(s)'' who have responsibilities for security and account management requirements for a facility's QualityNet account. We did not propose any changes to this policy in the proposed rule.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533 through 70534), we codified these requirements regarding participation status for the ASCQR Program at § 416.305. We did not propose any changes to these policies in the proposed rule.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Data Collection and Submission

a. Background

We previously codified our existing policies regarding data collection and submission under the ASCQR Program at § 416.310.

b. Requirements for Claims-Based Measures

(1) Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program at § 416.310(a)(1) and (2). We note that the previously finalized data processing and collection period requirements will apply to any future claims-based-measures using QDCs adopted in the ASCQR Program. We did not propose any changes to these requirements in the CY 2022 OPPS/ASC proposed rule.

(2) Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59472) (and the previous rulemakings cited therein), as well as 42 CFR 416.310(a)(3) and 42 CFR 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. As noted in section XVI.D.1.b. of this final rule with comment period, our policies for minimum threshold, minimum case volume, and data completeness requirements will apply to any future claims-based-measures using QDCs adopted in the ASCQR Program. We did not propose any changes to these policies in the proposed rule.

(3) Requirements Regarding Data Processing and Collection Periods for Non-QDC Based, Claims-Based Measure Data

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59136 through 59138) for a complete summary of the data

processing and collection requirements for the non-QDC based, claims-based measures. We codified the requirements regarding data processing and collection periods for non-QDC, claims-based measures for the ASCQR Program at § 416.310(b). We note that these requirements for non-QDC based, claims-based- measures apply to the following previously adopted measures:

- ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; and
- ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357).

We did not propose any changes to these requirements in the proposed rule.

c. Requirements for Data Submitted via an Online Data Submission Tool

(1) Requirements for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473) (and the previous rulemakings cited therein) and 42 CFR 416.310(c)(1) for our requirements regarding data submitted via a CMS online data submission tool. We are currently using the HQR System (formerly referred to as the QualityNet Secure Portal) to host our CMS online data submission tool, available at: *https://qualitynet.cms.gov/*. We note that in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473), we finalized expanded submission via the CMS online tool to also allow for batch data submission and made corresponding changes at § 416.310(c)(1)(i). We did not propose any changes to these policies for data submitted via a CMS online data submission tool in the proposed rule.

The following previously finalized measures require data to be submitted via a CMS online data submission tool for the CY 2021 payment determination and subsequent years:

- ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients;
- ASC–11: Cataracts: Improvement in Patients' Visual Function within 90 Days Following Cataract Surgery;
- ASC–13: Normothermia Outcome; and
- ASC–14: Unplanned Anterior Vitrectomy.

As discussed in section XVI.B.4.a.(2). of the CY 2022 OPPS/ASC proposed rule (86 FR 42271 through 42272), we proposed to require and resume data collection beginning with the CY 2023 reporting period/CY 2025 payment determination and subsequent years for the following four measures:

- ASC–1: Patient Burn;
- ASC–2: Patient Fall;
- ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and
- ASC–4: All-Cause Hospital Transfer/Admission.

Measure data for these measures would be submitted via the HQR System (formerly referred to as the QualityNet Secure Portal).

(2) Requirements for Data Submitted via a Non-CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75139 through 75140) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985 through 66986) for our requirements regarding data submitted via a non-CMS- online data submission tool (specifically, the CDC NHSN website). We codified our existing policies regarding the data collection periods for measures involving online data submission and the deadline for data submission via a non-CMS online data submission tool at § 416.310(c)(2). While we did not propose any changes to those policies in the CY 2022 OPPS/ASC proposed rule, we did propose policies specific to the proposed COVID–19 Vaccination Coverage Among HCP measure (ASC–20), for which data would be submitted via the CDC NHSN website.

(a) Form, Manner, and Timing for the COVID–19 Vaccination Coverage Among HCP Measure (ASC–20) Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination and Subsequent Years

For the COVID–19 Vaccination Coverage Among HCP measure (ASC–20), we proposed to require reporting data on the number of HCP who have received the completed vaccination course of a COVID–19 vaccine by each individual facility's CMS CCN.

We proposed that ASCs would report the measure through the NHSN web-based surveillance system.[559] Specifically, ASCs would use the COVID–19 vaccination data reporting modules in the NHSN HPS Component to report the number of HCP eligible to have worked at the ASC that week (denominator) and the number of those HCP who have received COVID–19 vaccination (numerator). Specific details on data submission for this measure can be found in the CDC's Overview of the Healthcare Safety Component, available at: *https://www.cdc.gov/nhsn/PDFs/slides/NHSN-Overview-HPS_Aug2012.pdf*.

For the COVID–19 Vaccination Among HCP measure (ASC–20), we proposed that ASCs would report the measure to the NHSN for at least one week each month, beginning with the January 1, 2022 through December 31, 2022, reporting period affecting CY 2024 payment determination and continuing with quarterly reporting deadlines for subsequent years. If ASCs report more than one week of data in a month, the most recent week's data would be used for measure calculation purposes. Each quarter, the CDC would calculate a summary measure of COVID–19 vaccination coverage from the reporting periods for the quarter.

With respect to public reporting, this quarterly average COVID–19 vaccination coverage would be publicly reported in four-quarter increments, when four quarters of data are available. Once four quarters are available, data will be refreshed on a quarterly basis with the most recent four quarters publicly displayed. For each CMS CCN, a percentage of the HCP who received a complete course of the COVID–19 vaccine would be calculated and publicly reported.

We did not receive comments on the form, manner, and timing for the COVID–19 Vaccination Coverage Among HCP Measure (ASC–20). We refer readers to section XVI.B.3.a.2. of this final rule with comment period for public comments received on the COVID–19 Vaccination Coverage Among HCP Measure (ASC–20).

After consideration of the public comments, we are finalizing our proposal to adopt the COVID–19 Vaccination Coverage Among HCP measure (ASC–20) with a modification to only publicly report the most recent quarter of data. Additionally, data will also be available for preview by ASCs for 30 days prior to being made publicly available. This would result in more meaningful information that is up to date and not diluted with older data.

d. Form, Manner, and Timing for Reporting the ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures

(1) Background

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79822 through 79824) for

[559] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures. In addition, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451), where we finalized a policy to delay implementation of the ASC–15a–e OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (2018 reporting period) until further action in future rulemaking.

(2) Addition of Data Collection Survey Modes of OAS CAHPS Measures Collection to Existing Three Modes

As discussed in section XVI.B.4.c. of the CY 2022 OPPS/ASC proposed rule (86 FR 42273), we proposed to begin data collection of five survey-based measures derived from the OAS CAHPS Survey for the ASCQR Program beginning with voluntary reporting for the CY 2023 reporting periods/CY 2025 payment determination,[560] followed by mandatory data collection and reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years. The OAS CAHPS Survey contains three OAS CAHPS composite survey-based measures and two global survey-based measures. We proposed requirements related to survey administration, vendors, and oversight activities.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79822 through 79825), we previously discussed the time, form, and manner in which OAS CAHPS information will be submitted. In the CY 2022 OPPS/ASC proposed rule (86 FR 42282 through 42284) we proposed two additional data collection modes (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents) [561] beginning with voluntary data collection and reporting for the CY 2023 reporting/CY 2025 payment determination and continuing for mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years. For more information about the modes of administration, we refer readers to the OAS CAHPS website: *https://oascahps.org*. We reiterate our clarification from when we adopted these measures in the CY 2017 OPPS/ASC final rule that, when implemented, ASCs that anticipate receiving more than 300 surveys would be required to either: (1) Randomly sample their eligible patient population; or (2) survey their entire OAS CAHPS eligible patient population (81 FR 79809). We also refer readers to section XV.D.4.b of this CY 2022 OPPS/ASC proposed rule where we describe our similar policy for the Hospital OQR Program.

(a) Survey Requirements

The data collection for the survey currently has three administration methods: (1) Mail-only; (2) telephone-only; and (3) mixed mode (mail with telephone follow-up of nonrespondents). We refer readers to the Protocols and Guidelines Manual for the OAS CAHPS Survey (*https://oascahps.org/Survey-Materials*) for materials for each mode of survey administration. In the CY 2018 OPPS/ASC final rule with comment period, we expressed interest in investigating the feasibility of offering the OAS CAHPS Survey using a web-based format (82 FR 59451). As a result, we designed a mode experiment to assess the impact of adding web-based survey administration. This mode experiment tested five administration modes with patients who receive outpatient surgical care: (1) Mail-only; (2) telephone-only; (3) web-only; (4) web with mail follow-up; and (5) web with a telephone follow-up. Data collection was completed in the fall of 2019. Response rates by mode in the experiment were: 35 percent (mail-only); 19 percent (telephone-only); 29 percent (web-only); 39 percent (web with mail follow-up); and 35 percent (web with telephone follow-up).

Based on these results, in addition to the three previously established modes, in the CY 2022 OPPS/ASC proposed rule (86 FR 42282 through 42283) we proposed to incorporate two additional administration methods: (1) Web with mail follow-up of non-respondents; and (2) web with telephone follow-up of non-respondents. This would allow a total of five modes of survey administration for reporting beginning with voluntary data collection and reporting as part of the ASCQR Program for the CY 2023 reporting period [562] and continuing for mandatory data collection and reporting for the CY 2024 reporting period/CY 2026 payment determination—the first year the survey would be required—and thereafter. We did not propose a purely web-based format at this time because the use of a web-based mode is included in the two mixed modes options being proposed and the purely web-based format would create response bias since not all patients have the ability to respond by web.

For all five proposed modes of administration as part of the ASCQR Program, we proposed that data collection must be initiated no later than 21-calendar days after the month in which a patient has a surgery or procedure at an ASC and completed within 6 weeks (42 days) after initial contact of eligible patients begins, beginning with voluntary data collection and reporting in the CY 2023 reporting period/CY 2025 payment determination and subsequent years. Under this policy, ASCs, via their CMS-approved survey vendors, must make multiple attempts to contact eligible patients unless the patient refuses or the ASC/vendor learns that the patient is ineligible to participate in the survey. In addition, we proposed that ASCs, via their CMS-approved- survey vendor, collect survey data for eligible patients using the established quarterly deadlines to report data to CMS for each data collection period, unless the ASC has been exempted from the OAS CAHPS Survey requirements under our minimum case volume for program participation [563] or our OAS CAHPS low-volume exemption policy, which exempts ACS that treat fewer than 60 survey-eligible patients during the ''eligibility period,'' (which is the calendar year before the data collection period (81 FR 79806)), that submit the participation exemption request form, which will be made available on the OAS CAHPS Survey website (*https://oascahps.org*) on or before May 15 of the data collection year. As finalized previously, all exemption requests would be reviewed and evaluated by CMS (81 FR 79806). For ASCs with minimum case volumes, but without a low-volume exemption, these

[560] As stated in section XVI.B.4.c. of the CY 2022 OPPS/ASC proposed rule, ''we note that National OAS CAHPS voluntary reporting is independent of the ASCQR Program, but the submission process will otherwise remain unchanged. This proposal is intended to clarify that voluntary reporting of OAS CAHPS would begin as part of the ASCQR program in the CY 2023 reporting period until mandatory reporting would begin in the CY 2024 reporting period, if both proposals are finalized''.

[561] The two additional modes will be available as part of National OAS CAHPS voluntary reporting in 2022.

[562] As stated in section XVI.B.4.c. of the CY 2022 OPPS/ASC proposed rule, ''we note that the two modes (web with mail follow-up of non-respondents; and web with telephone follow-up of non-respondents) will be available beginning in CY 2022 for National OAS CAHPS voluntary reporting, and then if finalized, available as part of ASCQR Program beginning in the CY 2023 reporting period and subsequent years''.

[563] ASCs with fewer than 240 Medicare claims (Medicare primary and secondary payer) per year during an annual reporting period for a payment determination year are not required to participate in the ASCQR Program for the subsequent annual reporting period for that subsequent payment determination year. See 42 CFR 416.305.

submission deadlines would be posted on the OAS CAHPS Survey website (*https://oascahps.org*). Late submissions would not be accepted.

As discussed in more detail below, compliance with the OAS CAHPS Survey protocols and guidelines, including this monthly data collection requirement as part of each quarterly data submission, would be overseen by CMS or its contractor who would receive approved vendors' monthly submissions, review the data, and analyze the results. As stated previously (81 FR 79805), all data collection and submission for the OAS CAHPS Survey measures would be reported at the CCN level, and if data collection and reporting becomes mandatory in CY 2024 reporting period/CY 2026 payment determination as proposed, under this proposal, all eligible ASCs in a CCN would be required to participate in the OAS CAHPS Survey, except for those that meet and receive an exception for having fewer than 60 survey-eligible-patients during the year preceding the data collection period (81 FR 79806). Therefore, we previously finalized the survey data reported for a CCN must include eligible patients from all eligible ASCs covered by the CCN; or if more than 300 completed surveys are anticipated, an ASC can choose to randomly sample their eligible patient population (81 FR 79817).

In the CY 2022 OPPS/ASC proposed rule (86 FR 42283 through 42284), we also proposed that survey vendors acting on behalf of ASCs must submit data by the specified data submission deadlines, which generally would be posted on the Outpatient and Ambulatory Surgery CAHPS Survey website located at *https://oascahps.org/Data-Submission/Data-Submission-Deadlines*. If an ASC's data are submitted after the data submission deadline, it would not fulfill the OAS CAHPS quality reporting requirements. Therefore, in regard to any OAS CAHPS reporting, we would strongly encourage ASCs to be fully appraised of the methods and actions of their survey vendors, especially the vendors' full compliance with OAS CAHPS Survey administration protocols, and to carefully inspect all data warehouse reports in a timely manner.

We reiterate that the use of predictive or auto dialers in telephonic survey administration is governed by the Telephone Consumer Protection Act (TCPA) (47 U.S.C. 227) and subsequent regulations promulgated by the Federal Communications Commission (FCC) (47 CFR 64.1200) and Federal Trade Commission. We refer readers to the FCC's declaratory ruling released on July 10, 2015 further clarifying the definition of an auto dialer, available at: *https://apps.fcc.gov/edocs_public/attachmatch/FCC-15-72A1.pdf*. In the telephone-only and mixed mode survey administration methods involving telephone, ASCs and vendors must comply with the regulations discussed above, and any other applicable regulations. To the extent that any existing CMS technical guidance conflicts with the TCPA or its implementing regulations regarding the use of predictive or auto dialers, or any other applicable law, CMS would expect vendors to comply with applicable law.

We received comments on these topics.

Comment: A commenter supported the proposal that the OAS CAHPS Survey data collection must be initiated no later than 21-calendar days after the month in which a patient has a surgery or procedure at a hospital/facility and completed within 6 weeks (42 days) after initial contact of eligible patient begins, beginning with voluntary reporting in the CY 2023 reporting period/CY 2025 payment determination and for subsequent years.

Response: We thank the commenter for its support.

Comment: Many commenters supported the two additional survey administration modes taking advantage of web-based technology: Web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents. Among the reasons for support were the belief that these additional modes will enable providers to reach a larger patient population, to receive more and timelier information to improve patient experience, to reduce burden associated with this measure, and to provide greater flexibility for providers to collect data and patients to respond. A few commenters encouraged CMS to monitor the data and patient response rates, particularly of the two additional web-based survey modes, and data.

Response: We thank the commenters for their support. We agree that as we expand the use of additional OAS CAHPS Survey modes, it will be important to monitor data, patient responses, and ensure that the OAS CAHPS Survey is refined as appropriate.

Comment: A few commenters recommended clarifying how CMS could distribute the web-based mode and suggested addressing how smart phones, email and texting could promote distribution of the survey.

Response: We thank the commenters for their feedback. Information regarding how OAS CAHPS Survey vendors may utilize the two web-based modes with telephone or mail follow-up, respectively, will be available on the OAS CAHPS website (*https://oascahps.org/*).

Comment: Many commenters appreciated the proposal for the additional two new mixed mode options that include web-based collection, but believe that there needs to be a web-only or additional digital modes to reduce financial burden of the survey and make the survey easier for patients to complete. Several commenters recommended that CMS should permit a web-only survey administration mode and noted that web-only would likely be popular form of administration, has a better response rate, could achieve minimum surveys more efficiently than telephone only, and would also reduce the financial burden of administration. One commenter specifically noted that these modes of survey distribution could help reach younger and minority populations.

Response: We thank the commenters for their feedback. We agree that the web-based mode interactions with smart phones, email, texting, and other electronic distribution create the potential for new and engaging ways to connect with patients, especially to traditionally underserved communities. We believe that the potential to expand and increase access to patient feedback is of the utmost importance and will continue to study potential refinement to methods of contact for the OAS CAHPS Survey.

Comment: A few commenters supported a web-only administration and noted that access to the internet should not limit the adoption of a web-only mode because neither telephone nor physical mail are available to everyone, and there is increasing access to technological resources.

Response: We thank the commenters for their feedback. We agree that no one mode of administration will work for every patient, which is why we are going to include five modes of survey administration. As we stated in the CY 2022 OPPS/ASC proposed rule (86 FR 42283), we did not propose a purely web-based format at this time because the use of a web-based mode is included in the two mixed modes options being proposed and the purely web-based format would create response bias since not all patients have access and the ability to respond via website. These two modes offer respondents the opportunity to respond via web-modes, but we believe that providing the additional follow-up provides patients with a greater opportunity to respond to the OAS CAHPS Survey, if they so choose. We will continue to review

digital-only modes of administration and seek to propose additional modes that are supported by research.

Comment: A commenter supported the use of web-based survey modes as an important survey option, but recommended that CMS ensure that patients are clear what information the OAS CAHPS Survey is seeking.

Response: We appreciate the commenters support for the web-based survey modes. We believe that patients will understand the web-based modes and be able to respond to the OAS CAHPS Survey. We also think patients will be able to associate the OAS CAHPS Survey with the appropriate facility and service that they received. As we stated in response to commenters who opposed mandatory reporting of the OAS CAHPS Survey in section XVI.B.4.c.(1) of this final rule with comment period, we believe that the information provided in the OAS CAHPS Survey ''Instructions'' is sufficient to inform the patient regarding the purpose of the OAS CAHPS Survey and provides sufficient instruction and details for the patient to correctly identify and relate the survey to the facility and procedure that patient received. CMS began developing the Outpatient and Ambulatory Surgery Survey in 2012 using the principles and guidelines established by the Agency for Healthcare Research and Quality's (AHRQ) CAHPS program and AHRQ approved this instrument as a CAHPS survey in February 2015.[564]

Comment: Many commenters opposed the requirement of 300 completed surveys as burdensome and requested that CMS set the initial requirement at 100 surveys.

Response: We are committed to ensuring high reliability in publicly reported OAS CAHPS Survey results. Acceptable methods of sampling survey-eligible patients can be found in Chapter IV-Sampling Procedures of the Protocols and Guidelines Manual at *https://oascahps.org/Survey-Materials*. We refer readers to our discussion on the reliability criterion that resulted in the 300 completed survey and 60-patient eligible threshold in the CY 2017 OPPS/ASC final rule (81 FR 79809 through 79810).

Currently, the target number of completed interviews for ASCs is 300 annually, or 25 per month. The target of 300 completed surveys for analysis is derived from the formula for the precision of a proportion with the estimate at 0.5, the confidence interval of about ±0.05, and a confidence level of 95 percent. If a facility's patient volume is too small to yield 300 completed surveys per year, a census of patients is surveyed and participation in public reporting is possible. If participation drops below 100 completed surveys, a footnote is applied to the publicly reported data indicating that the scores should be used with caution as the number of surveys may be too low to accurately reflect the facility's performance.

If the target number of completed interviews for ASCs were reduced to 200 completes annually, or about 17 per month, the precision of the estimate would be lower. The confidence interval would be ±7 percent. Given the smaller size of ASCs and specialization of services, we are finalizing a revised target number of completes, reducing it to 200 completes annually. We now believe that the 200 surveys will provide the appropriate balance of ensuring sufficient confidence in the results of the OAS CAHPS Survey, such that facilities will receive important patient feedback, while still reducing the overall burden of the OAS CAHPS Survey. We believe that this burden reduction is important as ASCs continue to respond to COVID–19. While we expect this reduction from 300 to 200 completed to be permanent, we will continue to assess whether the 200 completed surveys amount ensures appropriate levels of confidence in the OAS CAHPS Survey results and propose additional further modifications in future rulemaking.

As a reminder, under the current protocol, Medicare-certified HOPDs and ASCs that treat fewer than 60 survey-eligible patients during the same 12-month eligibility period have the option to submit a request for exemption from participating in the OAS CAHPS Survey. Also, ASCs that qualifies for an exemption from the ASCQR Program because they had fewer than 240 Medicare claims (Medicare primary and secondary payer) in the year prior to the data collection year for the applicable payment determination would also qualify for the exemption from the OAS CAHPS Survey for the same time period. These ASCs are not required to submit a participation exemption request form for the OAS CAHPS Survey for the same time period.

Comment: A commenter requested additional information on whether ASCs will be penalized for failure to reach the minimum number of required surveys because patients simply choose not to respond to OAS CAHPS.

Response: We agree with commenters that patient response is largely out of the control of the facility. We note that we did not propose to penalize ASCs for patients' decision not to complete the survey. An ASC will not receive a payment reduction as long as it participates in the survey, its vendor administers the survey according to the OAS CAHPS Survey Protocol and Guidelines Manual and submits that data to CMS by the data submission deadline.

Comment: A commenter strongly recommended that CMS reconsider their position on respondent confidentiality and remove the requirement to include the question on consent to share identifying information from the OAS CAHPS Survey if the facility is interested in receiving patient-level response data connected to the patient's identifying data. Another commenter explained that if facilities understood the patient, they could more easily provide their employees immediate, and targeted improvement training. The commenter recommended that CMS align the OAS CAHPS patient confidentiality rules with HCAHPS, which allows for the release of patient-level data for quality improvement purposes with the stipulation that the patient identity should not be shared with direct care staff. A commenter expressed concern about a question on the OAS CAHPS Survey that seeks information on ''Consent to Share Identifying Information'' because they believe it limits the ability to identify trends and thereby limits opportunities.

Response: While the desire to have patient identifying information to develop responsive training and remediation steps is admirable, we believe that patient confidentiality is an important aspect to the OAS CAHPS Survey. The administration protocols for OAS CAHPS follow protocols for CAHPS® Surveys, restricting the release of patient-level data if the patient has not consented. We note that, for the Hospital IQR Program, because hospitals can self-administer the HCAHPS Survey, we do not state that patients' responses and identifying information will not be shared with the hospital. However, for surveys administered via a third-party vendor, the survey is not linked to a sample patient's name unless the patient gives his or her consent. We note that facilities may choose to add the ''Consent to Share'' question to the OAS CAHPS Survey. This question asks whether a patient gives permission for their name to be linked to their survey responses. However, we note that each facility should consult with its own

[564] *See* CAHPS Outpatient and Ambulatory Surgery Survey. Content last reviewed July 2019. Agency for Healthcare Research and Quality, Rockville, MD. *https://www.ahrq.gov/cahps/surveys-guidance/oas/index.html.*

counsel to ensure compliance with applicable privacy and security laws.

Comment: A commenter recommended that CMS revise the OAS CAHPS patient eligibility definition such that it is based on a set of consistently knowable criteria and does not rely on Current Procedural Terminology (CPT) codes as the primary method to determine eligibility.

Response: The OAS CAHPS Survey is administered to all eligible patients or a random sample thereof who had at least one outpatient surgery/procedure during the applicable month. We acknowledge the concern about the use of CPT codes, including those for procedures that patients may not perceive as surgery, and note that we will consider this issue. We note that many CPT codes have been excluded from inclusion in the OAS CAHPS Survey, including services like application of a cast or splint, in order to ensure that only patients receiving applicable procedures are surveyed.[565] We thank the commenters and will take all comments under consideration as we craft future policy for the OAS CAHPS Survey. As materials are updated, they will be posted here: *https://oascahps.org/General-Information/Announcements*.

After consideration of the public comments we received, we are finalizing this proposal with modification. The annual required number of surveys that must be reported for an ASC to successfully complete the measure is reduced from 300 to 200, and if more than 200 completed surveys are anticipated, an ASC can choose to randomly sample their eligible patient population.

(b) Vendor Requirements

We did not propose new vendor requirements, but reiterate the vendor requirements finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79823 through 79824) to ensure that patients respond to the survey in a way that reflects their actual experiences with outpatient care, and is not influenced by the ASC. We finalized that ASCs must contract with a CMS-approved OAS CAHPS Survey vendor to conduct or administer the survey. We believe that a neutral third-party should administer the survey for ASCs, and it is our belief that an experienced survey vendor will be best able to ensure reliable results. CAHPS Survey-approved vendors are also already used or required in the following CMS quality programs: The Hospital Inpatient Quality Reporting Program (71 FR 68203 through 68204); the Hospital Value-Based Purchasing (VBP) Program (76 FR 26497, 26502 through 26503, and 26510); the End Stage Renal Disease Quality Improvement Program (76 FR 70269 through 70270); the Home Health QRP (80 FR 68709 through 68710); and the Hospice QRP (80 FR 47141 through 47207).

Information about the list of approved survey vendors and how to authorize a vendor to collect data on an ASC's behalf is available through the OAS CAHPS Survey website, available at: *https://oascahps.org*. The web portal has both public and secure (restricted access) sections to ensure the security and privacy of selected interactions. As mentioned earlier, requirements for survey vendors were previously finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79793 through 79794) and codified at § 416.310(e)(2). ASCs will need to register on the OAS CAHPS Survey website (*https://oascahps.org*) in order to authorize the CMS-approved vendor to administer the survey and submit data on their behalf. Each ASC must then administer (via its vendor) the survey to eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (*https://oascahps.org*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website.

Comment: Several commenters opposed the requirement that OAS CAHPS Survey be administered by third party vendors. Reasons given included that requiring third-party vendors increases the expense of the survey, vendors may not be fiduciaries for ASCs, the use of vendors adds unnecessary bureaucracy, vendor errors could negatively impact ASCs results and that ASCs are capable of collecting information and reporting data. Another commenter stated that of the number of approved vendors may not be prepared to accept the additional volume of work from the nation's ASCs. Another commenter stated its belief that the False Claims Act is sufficient to ensure compliance.

Response: In order to meet the survey administration requirements for these measures, the ASC must administer the OAS CAHPS Survey in accordance with the requirements listed in the OAS CAHPS Survey Protocols and Guidelines Manual.[566]

OAS CAHPS Survey requires that the survey be administered by an approved survey vendor to ensure that patients respond to the survey in a way that reflects their actual experiences with outpatient surgical care and is not influenced by the facility. If vendors were removed as neutral third parties, there could be concerns of objectivity and bias.

We believe that OAS CAHPS Survey vendors have gained experience during the voluntary reporting as part of the voluntary National OAS CAHPS program, and approved vendors will be able to support ASCs. We post the list of the approved OAS CAHPS Survey vendors on *https://oascahps.org*, and we encourage ASCs to contact vendors for cost and service information pertaining to OAS CAHPS Survey as there may be differences among vendors and multiple modes of conducting the survey provide greater economical choice.

We acknowledge that it is possible an ASC could fail to meet the requirements under the ASC–15a–e Survey-based measures if its vendor fails to administer the survey properly or submit the required data to CMS by the data submission deadline. However, we continue to believe that a neutral third party should administer the survey for ASCs, and it is our belief that an experienced survey vendor will be best able to ensure reliable results. We encourage all ASCs to be fully apprised of the methods and actions of their survey vendors—especially the vendors' full compliance with the OAS CAHPS Survey Administration protocols—and to carefully inspect all data warehouse reports in a timely manner. After the survey vendor submits the data to the OAS CAHPS Data Center, we strongly recommend that ASCs promptly review their two OAS CAHPS feedback reports and submit corrections under the process outlined in the OAS CAHPS Protocol and Guidelines Manual.[567] These reports enable an ASC to ensure that its survey vendor has submitted the data on time, the data has been accepted into the OAS CAHPS Data Center, and the data accepted into the OAS CAHPS Data Center are complete and accurate. Finally, we note that submission of complete, accurate, and timely data is the responsibility of the ASC. ASCs should check-in regularly with survey vendors to ensure that vendors are properly submitting timely survey data.

[565] *https://oascahps.org/General-Information/Announcements*.

[566] Current Survey Materials (*oascahps.org*).

[567] OAS CAHPS Survey Materials, including the OAS CAHPS Protocol and Guidelines Manual are available at Current Survey Materials (*oascahps.org*).

e. ASCQR Program Data Submission Deadlines

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86191) we finalized that all program deadlines falling on a nonwork day be moved forward consistent with section 216(j) of the Act, 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days.'' Specifically, the Act indicates that all deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day, all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order, shall be extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order (42 U.S.C. 416(j)). We codified this policy at § 416.310(f). We did not propose any changes to this policy in the proposed rule.

f. Review and Corrections Period for Measure Data Submitted to the ASCQR Program

(1) Review and Corrections Period for Data Submitted via a CMS Online Data Submission Tool

Under the ASCQR Program, for measures submitted via a CMS online data submission tool, ASCs submit measure data to CMS from January 1 through May 15 during the calendar year subsequent to the current data collection period (84 FR 61432).[568] For example, ASCs collect measure data from January 1, 2020 through December 31, 2020 and submit these data to CMS from January 1, 2021 through May 15, 2021. ASCs may begin submitting data to CMS as early as January 1. ASCs are encouraged, but not required, to submit data early in the submission period so that they can identify errors and resubmit data before the established submission deadline.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86191 through 86192), we finalized the formalization of that process and established a review and corrections period similar to what was finalized for the Hospital OQR Program in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86184) for data submitted via the CMS web-based tool. For the ASCQR Program, we finalized the implementation of a review and corrections period which runs concurrently with the data submission period beginning with the effective date of this rule. During this review and corrections period, ASCs may enter, review, and correct data submitted directly to CMS. However, after the submission deadline, ASCs are not allowed to change these data. We codified this review and corrections period at § 416.310(c)(1)(iii). We did not propose any changes to this policy in the proposed rule.

(2) Review and Corrections Period for the OAS CAHPS Measures

Each ASC administers (via its vendor) the survey to all eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (available at: *https://oascahps.org*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website as stated above in section XVI.D.1.d.(2).(b). of this final rule with comment period. Data cannot be altered after the data submission deadline but can be reviewed prior to the submission deadline (81 FR 79822 through 79823).

g. ASCQR Program Reconsideration Procedures

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (82 FR 59475) (and the previous rulemakings cited therein) and 42 CFR 416.330 for the ASCQR Program's reconsideration policy. We did not propose any changes to this policy in the proposed rule.

h. Extraordinary Circumstances Exception (ECE) Process for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59474 through 59475) (and the previous rulemakings cited therein) and 42 CFR 416.310(d) for the ASCQR Program's policies for extraordinary circumstance exceptions (ECE) requests. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59474 through 59475), we: (1) Changed the name of this policy from ''extraordinary circumstances extensions or exemption'' to ''extraordinary circumstances exceptions'' for the ASCQR Program, beginning January 1, 2018; and (2) revised § 416.310(d) of our regulations to reflect this change. We will strive to complete our review of each request within 90 days of receipt. We did not propose any changes to this policy in the proposed rule.

E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74493) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2022, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the productivity-adjusted hospital market basket update factor. The productivity adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The productivity-adjusted hospital market basket update is the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023). Under the ASCQR Program, in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase in certain payment rates under the ASC payment system shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: A full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national

[568] ASCQR Program Data Submission Deadlines. Available at: *https://qualitynet.cms.gov/asc/data-submission#tab2.*

unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the productivity adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to the proposed rule, which are available via the internet on the CMS website): ''A2'', ''G2'', ''P2'', ''R2'' and ''Z2'', as well as the service portion of device-intensive procedures identified by ''J8'' (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2'', ''G2'', ''J8'', ''P2'', ''R2'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, radiology services and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (generally those performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology when provided integral to covered ASC surgical procedures. In the CY2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we have noted our belief that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In that final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: The wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015 through CY 2021 OPPS/ASC final rules with comment period we did not make any other changes to these policies. We proposed the continuation of these policies for CY 2022 in the CY 2022 OPPS/ASC proposed rule (86 FR 42284 through 42285), did not receive any public comments on these policies, and are finalizing the continuation of these policies for CY 2022.

XVII. Radiation Oncology Model

A. Introduction

The purpose of this final rule with comment period is to finalize provisions related to the delay of the Radiation Oncology (RO) Model and finalize modifications to certain policies proposed in the CY 2022 OPPS/ASC proposed rule.

Section 1115A of the Act authorizes the Center for Medicare and Medicaid Innovation (Innovation Center) to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs. Under the Medicare fee-for-service (FFS) program, Medicare generally makes a separate payment to providers and suppliers for each item or service furnished to a beneficiary during the course of treatment. Because the amount of payments received by a provider or supplier for such items and services varies with the volume of items and services furnished to a beneficiary, some providers and suppliers may be financially incentivized to inappropriately increase the volume of items and services furnished to receive higher payments. Medicare FFS may also detract from a provider's or supplier's incentive to invest in quality improvement and care coordination activities if it means those activities will result in payment for fewer items and services. As a result, care may be fragmented, unnecessary, or duplicative.

The RO Model is designed to test whether prospective episode-based payments for radiotherapy (RT) services (also referred to as radiation therapy services) will reduce Medicare program expenditures and preserve or enhance quality of care for beneficiaries. As radiation oncology is highly technical and furnished in well-defined episodes, and because patient comorbidities generally do not influence treatment delivery decisions, we believe that radiation oncology is well-suited for testing a prospective episode payment model. Under the RO Model, Medicare will pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and

technical RT services furnished during a 90-day episode to Medicare FFS beneficiaries diagnosed with certain cancer types. The RO Model will include approximately 30 percent of all eligible RO episodes nationally. Under the RO Model, the episode payment amounts for included cancer types that are treated with RT services included in the RO Model will be the same for hospital outpatient departments (HOPDs) and freestanding radiation therapy centers.

The RO Model will offer RO participants the opportunity to examine and better understand their own care processes and patterns with regard to RO beneficiaries receiving included RT services for included cancer types. We believe that RO participants in the RO Model will have a significant opportunity to redesign care and improve the quality of care furnished to RO beneficiaries receiving these services. We believe the RO Model will further the agency's goal of increasing the extent to which CMS initiatives pay for value and outcomes, rather than for volume of services alone, by promoting the alignment of financial and other incentives for health care providers caring for beneficiaries receiving treatment for cancer. Payments that are made to health care providers for assuming financial accountability for the cost and quality of care create incentives for the implementation of care redesign among model participants and other providers and suppliers.

B. Background

CMS is committed to promoting higher quality of care and improving outcomes for Medicare beneficiaries while reducing costs. Accordingly, as part of that effort, we have in recent years undertaken a number of initiatives to improve the care of cancer patients, most notably with our Oncology Care Model. We believe that a model in radiation oncology will further these efforts to improve cancer care for Medicare beneficiaries and reduce Medicare expenditures. RT is a common treatment, received by nearly two thirds of all patients undergoing cancer treatment, and it is typically furnished by a radiation oncologist. As described in the 2017 Report to Congress: ''Episodic Alternative Payment Model for Radiation Therapy Services'', and also in the ''Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' (84 FR 34490) (hereinafter referred to as the ''Specialty Care Models proposed rule''), because there are differences in the underlying methodologies used for rate setting in the OPPS and Physician Fee Schedule (PFS), there often are differences in the payment rate for the same RT service depending on whether the service is furnished in a freestanding radiation therapy center paid under the PFS, or an HOPD paid under the OPPS. This is called the site-of-service payment differential, and stakeholders from freestanding radiation therapy centers have asserted that such differentials between HOPDs and freestanding radiation therapy centers are unwarranted because the actual treatment and care received by patients for a given modality is the same in each setting. For these reasons, the RO Model is designed to test whether making site-neutral, prospective, episode-based payments to HOPDs, physician group practices (PGPs), and freestanding radiation therapy centers for RT episodes of care preserves or enhances the quality of care furnished to Medicare beneficiaries while reducing or maintaining Medicare program spending.

On September 29, 2020, we published in the **Federal Register** the final rule titled ''Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' (85 FR 61114) (hereinafter referred to as the ''Specialty Care Models final rule'') and codified policies at 42 CFR part 512. Due to the state of the public health emergency (PHE) for the Coronavirus disease 2019 (COVID–19) pandemic in Fall 2020, CMS revised the RO Model's model performance period to begin on July 1, 2021, and to end December 31, 2025, in the CY 2021 Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs final rule with comment period (85 FR 85866) (hereinafter referred to as ''CY 2021 OPPS/ASC final rule''), giving RO participants an additional 6 months to prepare for the RO Model. As we stated at 85 FR 86261, the delay was intended to give RO participants additional time to learn the RO billing requirements and train staff on new procedures. It was also intended to give more time to RO participants to understand their participant-specific case mix and historical experience adjustments and the payment they expect to receive under the RO Model. It was not CMS' intention to delay the RO Model until the COVID–19 PHE ended. In the CY 2021 OPPS/ASC final rule, we changed the duration of the model performance period from 5 years to 4.5 years, changed the timelines for the submission of clinical data elements (CDEs), quality measures and Certified Electronic Health Record Technology (CEHRT) requirements, and modified the eligibility dates of the RO Model as an Advanced Alternative Payment Model (APM) and Merit-based Incentive Payment System (MIPS) APM (85 FR 85866).

Section 133 of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116–260) (hereinafter referred to as ''CAA, 2021''), enacted on December 27, 2020, includes a provision that prohibits implementation of the RO Model before January 1, 2022. This Congressional action supersedes the RO Model delayed model performance period established in the CY 2021 OPPS/ASC final rule with comment period. To respond to the congressionally mandate delay, we proposed provisions related to the additional delayed implementation of the RO Model due to the CAA, 2021, including a proposed model performance period starting on January 1, 2022, with a 5-year model performance period, as well as modifications to certain RO Model policies not related to the delay, in the CY 2022 OPPS/ASC proposed rule.

We proposed to modify §§ 512.205, 512.210, 512.217, 512.220, 512.230, 512.240, 512.245, 512.250, 512.255, 512.275, 512.280, and 512.285 and add §§ 512.292 and 512.294. We received approximately 554 timely pieces of correspondence in response to our solicitation of public comments on the proposed rule from 143 commenters. We are finalizing the majority of the proposals without modification, and there are two proposals that we are finalizing with modification. These include the definitions for RO Track One and RO Track Two, as well as the extreme and uncontrollable circumstances (EUC) policy. There were a few sections where we asked for comments but noted we would not respond to those comments in the rule. There were also points of clarification that we did not ask for comments on. We will not be responding to comments in either of those cases in this rule. We also note that some of the public comments were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed in this final rule with comment period. Many were previously addressed in the Specialty Care Models final rule (85 FR 61114) and/or a set of Frequently Asked Questions on the RO Model website. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule with comment period under the appropriate heading.

C. RO Model Regulations

1. Model Performance Period

In the Specialty Care Models final rule, we specified at § 512.205 that the model performance period would last five performance years, beginning January 1, 2021, and ending December 31, 2025 (85 FR 61367). We finalized that each PY is the 12-month period beginning on January 1 and ending on December 31 of each CY during the model performance period, and no new RO episodes may begin after October 3, 2025, in order for all RO episodes to end by December 31, 2025.

In the CY 2021 OPPS/ASC final rule, we amended the definition of model performance period, specifying that it would begin July 1, 2021 and end on December 31, 2025, and we amended the definition of PY to mean the 6-month period beginning on July 1, 2021 and ending on December 31, 2021, and the 12-month period beginning on January 1 and ending on December 31 of each subsequent year (2022 through 2025) during the model performance period (85 FR 86261).

The CAA, 2021, enacted on December 27, 2020, includes a provision that prohibits implementation of the RO Model prior to January 1, 2022. In the CY 2022 OPPS/ASC proposed rule, CMS proposed to begin the RO Model as soon as we are permitted to do so by law, on January 1, 2022, as we continue to believe that a prospective episode payment model is needed and well suited to be tested in the radiation oncology space. CMS also proposed to modify the model performance period to begin on January 1, 2022, and end December 31, 2026, as described in the proposed definitions in section XVIII.C.2 of the CY 2022 OPPS/ASC proposed rule (86 FR 42290). If finalized as proposed, no new RO episodes would begin after October 3, 2026, in order for all RO episodes to end by December 31, 2026. We also proposed that each PY would be a 12-month period beginning on January 1 and ending on December 31 of each year during the model performance period, unless the initial model performance period starts mid-year, in which case PY1 would begin on that date and end on December 31 of that year (86 FR 42290).

We solicited public comments on our proposal in section XVIII.C.1 of the CY 2022 OPPS/ASC proposed rule (86 FR 42290).

The following is a summary of the public comments received on this proposal and our responses:

Comment: A few commenters supported the model performance period beginning on January 1, 2022. One of these commenters stated that the extra 12-month delay from the original implementation date of January 1, 2021 has provided sufficient time for RO Model participants to prepare and be able to meet the requirements for participation in the RO Model. Another commenter noted that the agency has been working on proposals for the RO Model for a number of years, stakeholders have provided comprehensive feedback, and they urged CMS to proceed with implementation on January 1, 2022. A commenter supported CMS' proposal to align each 12-month performance year with the calendar year, starting in 2022, as that will simplify the RO Model for RO participants.

Response: We thank these commenters for their support.

Comment: Many commenters commented that the model performance period should be further delayed. Of the commenters who suggested an alternative model performance period for the RO Model, a few commenters recommended delaying until mid-2022, some commenters recommended delaying until 2023, a couple commenters recommended delaying until the COVID–19 PHE has ended, and a few commenters suggested delaying until the calendar year after the PHE has ended. Many commenters noted that the extension of the COVID–19 PHE and the financial and operational challenges brought on by the COVID–19 PHE warrant an additional delay.

Response: We thank commenters for their comments on the model performance period for the RO Model. CMS proposed the earliest model performance period permitted under the CAA, 2021 because we believe in prioritizing a prospective episode payment model in the radiation oncology space in order to provide payment stability and promote high quality care for Medicare beneficiaries. Further, we do not find that it is appropriate to further delay the model performance period due to the COVID–19 PHE because it will be nearly 2 years into the COVID–19 PHE by January 1, 2022, when the RO Model is slated to begin. RO participants have been aware that they have been selected for participation in the RO Model since September 2020. Therefore, we believe that RO participants have had sufficient time to prepare for the RO Model and to adjust their workflows in light of the COVID–19 PHE. We also believe that delaying the model performance period further would penalize those RO participants who have been preparing to implement the RO Model, would further postpone RO participants' ability to participate in an Advanced APM and MIPS APM, and has the potential to generate confusion.

To address concerns related to the start of the model and the effects of the COVID–19 PHE, we are finalizing in section XVII.C.10. of this final rule with comment period an Extreme and Uncontrollable Circumstances (EUC) policy, codified at § 512.294, that would allow CMS flexibility in responding to national, regional, or local circumstances that adversely impact RO participants' ability to deliver care in accordance with the RO Model's requirements, including the COVID–19 PHE. As we proposed in section XVIII.C.10 of the CY 2022 OPPS/ASC proposed rule, in a national, regional, or local event, we would apply EUC policy only if the magnitude of the event calls for the use of special authority to help providers respond to the emergency and continue providing care. We stated that we would not use a bright-line test to assess all types of public health emergencies, disasters, or other extraordinary circumstances; application of the policy would be tailored to the specific circumstance and to the affected geographic areas. CMS will continue to monitor the impact of the COVID–19 PHE on RO participants. As proposed, if CMS invokes any of the EUC policies, related to the COVID–19 PHE or otherwise, we will communicate this decision via the RO Model website and written correspondence to RO participants.

Comment: Many commenters stated that they would not have sufficient time to prepare for the implementation of the RO Model, as there will be approximately two months between the publication of the CY 2021 OPPS/ASC final rule and the beginning of the proposed model performance period. A commenter noted that January 1, 2022 is fewer than 4 months away, and physician practices and their medical center administrations should have at least 12 months of notification of the final model requirements and definitions to prepare for their clinical implementation and related billing changes.

Response: We will have already delayed the model performance period twice: From January 1, 2021 to July 1, 2021, in the CY 2021 OPPS/ASC final rule (85 FR 85866); and from July 1, 2021 to January 1, 2022, in this final rule. CMS posted the RO Model's participating ZIP Code list in September of 2020 and noted in a subsequent rule (85 FR 85866) that the CBSAs selected for participation in the RO Model would not change due to the revised model performance periods. We also reiterated

our intent that the CBSAs selected for participation in the RO Model would not change due to the revised model performance period in the CY 2022 OPPS/ASC proposed rule (86 FR 42290). We believe that RO participants have had sufficient time to prepare for the implementation of the RO Model, as they have known that they would be required to be in the RO Model since the publication of the Specialty Care Model final rule in September of 2020 (85 FR 61149 through 61151). We also note that none of the modifications to the RO Model finalized in this final rule will change how the RO Model is operationalized. RO participants have therefore had over a year to prepare for the implementation of the RO Model, which we believe is sufficient.

Comment: A commenter noted that it may be challenging for some hospitals to prepare for a model performance period beginning January 1, 2022, particularly given the impact of the COVID–19 PHE, and encouraged CMS to be mindful of this strain and to monitor its impacts on model participants.

Response: We appreciate this commenter's concern regarding the COVID–19 PHE. We will have already delayed the model performance period twice, from January 1, 2021 to July 1, 2021 due to the COVID–19 PHE in the CY 2021 OPPS/ASC final rule (85 FR 85866), and subsequently to January 1, 2022 in this final rule, as required by the CAA, 2021. We will continue to monitor the RO Model's impacts on RO participants, as finalized in 85 FR 61257 through 61258.

Comment: A few commenters requested a delay to the model performance period to allow more time for radiation oncology Electronic Health Records (EHR) vendors to comply with the RO Model requirements and to test the functionality of these new software systems. These commenters stated that nearly all radiation oncology practices have separate management systems in addition to their practice's EHR; there are only two vendors nationwide that provide these EHR systems for radiation oncology; a new software build to capture the relevant fields can take between 12 and 18 months; and there are a limited number of vendor IT support staff whose services are necessary to facilitate these upgrades.

Response: As we discussed in the Specialty Care Models final rule (85 FR 61136), we agree with commenters' concerns that EHR vendors will need time to design, develop, build, test, validate, and implement the software to allow RO participants to fulfill the requirements of the RO Model in a streamlined manner through their EHR platforms. We understand that successful implementation of the RO Model may require many RO participants as well as software vendors to change EHR configurations, organizational policies, and end user workflows. However, we believe that we have provided sufficient time, since the publication of the Specialty Care Models final rule in September 2020, for RO participants and their EHR vendors to implement the software that RO participants may need to adhere to the RO Model requirements. We also note that although an RO participant may document these requirements using their EHR system if they wish, no changes to EHR systems are required for tracking compliance with RO Model requirements.

Comment: Many commenters requested delaying the model performance period to have more time to meet quality and CDE requirements. Many commenters stated that RO Model participants are only now learning additional details on quality and CDE requirements, which may require significant practice changes in order to ensure compliance. A couple commenters also asked that if the model performance period were to begin January 1, 2022, we delay some of the requirements, including quality measure and CDE reporting, and implement them after PY1.

Response: We thank commenters for their comments around delaying some of the requirements of the RO Model. RO participants were notified of their inclusion in the RO Model upon publication of the Specialty Care Models final rule in September 2020. RO participants have had more than a year to prepare for their participation in the RO Model, which we believe is sufficient.

In July 2021, CMS released the Quality Measure and Clinical Data Elements Guide on the RO Model website, along with the associated CDE templates. We have provided education and outreach support to encourage the efficient collection and submission of this data, including a webinar related to Model requirements in September 2021 to help participants prepare for the various requirements, and we have additional webinars planned specifically on the Quality Payment Program (QPP) and quality measures and CDEs. We believe we have provided RO participants with this information in sufficient time for them to prepare for the quality and reporting requirements.

Comment: Many commenters requested a delay to the model performance period in order to have more time to implement the billing processes required for the Model, which may require significant practice changes. Many commenters stated that RO Model participants are only now learning additional details on the billing requirements under the RO Model. A couple commenters recommended postponing the model performance period because providers need additional clarification around appropriate billing, which they believe CMS has not yet provided. One of these commenters maintained that the education seminars and tools CMS has provided to date were insufficient to prepare RO participants to execute the billing process under the RO Model.

Response: We believe that we have created a billing process that will be easily implemented within current systems because it is based on how FFS claims are currently submitted, which all RO participants should have experience submitting. We provided information on billing and coding changes under the RO Model in the Specialty Care Models final rule (85 FR 61205 through 61211). The RO Model-specific HCPCS codes were made public July 19, 2021. And the three modifiers and one condition code used for billing previously existed in the current PFS and OPPS claims systems and have addressed related questions in FAQs. We also hosted a RO Model Billing webinar on August 24, 2021, of which the slides and recording can be found on the RO Model website, *https://innovation.cms.gov/innovation-models/radiation-oncology-model*, and we hosted RO Model Billing Office Hours on August 31, 2021. Finally, we would encourage RO participants to access a billing guide document that restates the information provided in the aforementioned webinar available on the RO Model website in mid-November. We believe these resources provide sufficient guidance on implementing the billing process to RO participants, as we endeavored to explain the process in detail and answer RO participants' billing questions through these resources. We will continue to answer any billing questions RO participants may have, which can be submitted to *RadiationTherapy@cms.hhs.gov*. Further, we believe that RO participants have had adequate time to operationalize the Model's billing requirements, which are based on the current FFS claims systems, as RO participants have known they would be required to participate in the RO Model since the publication of the Specialty Care Models final rule in September of 2020 (85 FR 61149 through 61151).

Comment: A couple commenters offered an alternative proposal that the

RO Model should establish an implementation year, or ''PY0'', before the actual start of the model performance period to allow CMS to address complexities in the billing design, and allow participants to change workflows to align with the RO Model, utilize performance data from CMS to identify areas for transformation, receive additional education from CMS on RO Model parameters and meeting objectives, and allow providers and vendors additional time to operationalize data collection and reporting requirements.

Response: We appreciate the commenters' suggestions but, as discussed above, we will have already revised the model performance period twice. RO participants have known they would be required to participate in the RO Model since the publication of the Specialty Care Models final rule in September of 2020 (85 FR 61149 through 61151), so we believe that RO participants have had adequate time to prepare for the Model. We believe that a PY0 is unnecessary because RT providers and RT suppliers have had more than a year to prepare for the RO Model and its requirements and a PY0 would only further delay the model.

After considering public comments, we are finalizing as proposed that the model performance period will begin January 1, 2022 and end December 31, 2026. We are also finalizing as proposed that no new RO episodes may begin after October 3, 2026, in order for all RO episodes to end by December 31, 2026. We are also finalizing as proposed that each PY will be a 12-month period beginning on January 1 and ending on December 31 of each year during the model performance period, unless the initial model performance period starts mid-year, in which case PY1 will begin on that date and end on December 31 of that year.

We are also finalizing our proposed definition that the model performance period means the five PYs during which RO episodes must initiate and terminate. The model performance period begins on January 1, 2022 and ends on December 31, 2026, unless the RO Model is prohibited by law from starting on January 1, 2022, in which case the model performance period begins on the earliest date permitted by law that is January 1, April 1, or July 1.

Finally, we received no comments on our proposed definition for PY (performance year) to be each 12-month period beginning on January 1 and ending on December 31 during the model performance period, unless the model performance period begins on a date other than January 1, in which case PY1 will begin on that date and end on December 31 of that year. We are finalizing as proposed to codify this definition at § 512.205.

2. Definitions

Definitions for the RO Model are codified at § 512.205. We proposed to modify some of these definitions and add several new terms and definitions as described in section XVIII. of the CY 2022 OPPS/ACS proposed rule.

We proposed to modify the definition of the ''model performance period'' to mean the five PYs during which RO episodes must initiate and terminate. The model performance period would begin on January 1, 2022 and end on December 31, 2026, unless the RO Model is prohibited by law from starting on January 1, 2022, in which case the model performance period would begin on the earliest date permitted by law that is January 1, April 1, or July 1.

We proposed to modify the definition of ''PY'' (performance year) to mean each 12-month period beginning on January 1 and ending on December 31 during the model performance period, unless the model performance period begins on a date other than January 1, in which case, the first performance year (PY1) would begin on that date and end on December 31 of the same year.

We proposed to modify the definition of ''stop-loss reconciliation amount'' to mean the amount set forth in § 512.285(f) owed by CMS for the loss incurred under the Model to RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation.

We proposed to add a definition for ''EUC'' (extreme and uncontrollable circumstances) to correspond with the proposed EUC policy described in section XVIII.C.10 of the CY 2022 OPPS/ACS proposed rule. To describe how changes in CMS Certification Numbers (CCNs) and Tax Identification Numbers (TINs) are treated under the RO Model, which was described in section XVIII.C.5.g. of the CY 2022 OPPS/ACS proposed rule, we also proposed to add definitions for ''legacy CCN'' and ''legacy TIN''. And, to clarify how RO Model requirements align with the Quality Payment Program (QPP), we proposed to add definitions for ''Track One'' and ''Track Two'' as described in section XVIII.C.7. of the CY 2022 OPPS/ACS proposed rule.

We proposed to add a definition for ''baseline period'', specifying which episodes (dependent on the model performance period) are used in the pricing methodology. We proposed to define ''baseline period'' to mean the three calendar year (CY) period that begins on January 1 no fewer than 5 years but no more than 6 years prior to the start of the model performance period during which episodes must initiate in order to be used in the calculation of the national base rates, participant-specific professional and technical historical experience adjustments for the model performance period, and the participant-specific professional and technical case mix adjustments for PY1. The baseline period would be January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in CY 2022, in which case the baseline period would be adjusted according to the new model performance period (that is, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).

In the CY 2022 OPPS/ASC proposed rule, we solicited public comments on our proposed definitions. To the extent we have received comments relating to the definitions that we had proposed, we have responded to those comments in context throughout section XVII.C. of this final rule with comment period.

3. RO Model Participant Exclusions

At § 512.210(b), we exclude from the RO Model any PGP, freestanding radiation therapy center, or HOPD that furnishes RT only in Maryland; furnishes RT only in Vermont; furnishes RT only in United States (U.S.) Territories; is classified as an ambulatory surgical center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital; or participates in or is identified by CMS as eligible to participate in the Pennsylvania Rural Health Model (PARHM).

a. Pennsylvania Rural Health Model (PARHM)

We proposed in the CY 2022 OPPS/ASC proposed rule (86 FR 42290 through 42291) to modify § 512.210(b)(5) to exclude from the RO Model only the HOPDs that are participating in PARHM, rather than excluding both HOPDs that are participating in PARHM and those that have been identified by CMS as eligible to participate in PARHM. As we stated in the proposed rule, we continue to believe that HOPDs that are participating in PARHM should be excluded from the RO Model because these hospitals receive global budgets, and these global budgets would include payments for RT services and as such

would overlap with the RO Model payment. In the Specialty Care Models final rule, we also excluded HOPDs that are eligible to participate in the PARHM from the RO Model on the grounds that additional hospitals and CAHs may join PARHM in the future or may be included in the evaluation comparison group for that model (see 85 FR 61144).

However, as we stated in the CY 2022 OPPS/ACS proposed rule, after further consideration, we believe that including in the RO Model those HOPDs that have been identified as eligible to participate in PARHM, but that are not actually participating in PARHM because they are not currently a party to a PARHM participation agreement with CMS, would not affect the PARHM evaluation. First, such HOPDs do not receive global budgets under PARHM, so including these hospitals in the RO Model would not result in an overlap between PARHM payments and RO Model payments. Second, while we initially explored the potential for HOPDs that are eligible to participate in PARHM being included in that model's evaluation comparison group, we now expect that the PARHM comparison group will consist only of hospitals located outside of Pennsylvania because of selection constraints. Thus, we stated in the CY 2022 OPPS/ACS proposed rule that it is now our expectation that HOPDs that have been identified as eligible to participate in PARHM—all of which are located within the Commonwealth of Pennsylvania—would not be selected for the comparison group for the PARHM evaluation. Accordingly, we do not expect that including in the RO Model those HOPDs that have been identified as eligible to participate, but not actually participating in PARHM would affect the ability to detect the impact of PARHM on the cost and quality of care.

In addition, while it remains the case that hospitals and CAHs may join PARHM on an ongoing basis, hospitals and CAHs generally join PARHM at the start of a given CY. As described in the CY 2022 OPPS/ASC proposed rule, because the RO Model's PYs would align with CYs, we concluded in the CY 2022 OPPS/ACS proposed rule that it would be possible to update the RO Model exclusions for a given PY if an HOPD leaves or joins PARHM. For instance, we stated in the CY 2022 OPPS/ACS proposed rule that if a rural hospital identified as eligible to participate in PARHM later initiates its participation in PARHM by signing a PARHM participation agreement with CMS, then the HOPDs participating in PARHM as part of that participating rural hospital would be excluded from participation in the RO Model as of the start of the next CY quarter that follows the date that the HOPD begins participating in PARHM. (As we discuss further in response to comments in this section, we are clarifying in this final rule that the HOPDs participating in PARHM as part of that participating rural hospital would be excluded from participation in the RO Model as of the start of the CY quarter that includes the HOPD's start date in PARHM.) Similarly, we stated that if an HOPD no longer participates in PARHM as part of a participating rural hospital, and the HOPD otherwise meets the definition of an RO participant, then the HOPD would be required to participate in the RO Model as of the start of the next CY quarter.

We stated in the CY 2022 OPPS/ACS proposed rule that we would continue to use the list on the PARHM website at *https://innovation.cms.gov/initiatives/pa-rural-health-model/*, which is updated quarterly, to identify the hospitals that are participating in PARHM, and therefore identify the specific HOPDs excluded from participation in the RO Model. We therefore proposed that HOPDs that are identified as eligible to participate in PARHM, but that are not current PARHM participants, should be included in the RO Model if they are located in a CBSA selected for participation in the RO Model and that this exclusion of HOPDs associated with hospitals that participate in PARHM from the RO Model would apply only during the period of such participation.

We solicited public comments on our proposal to include HOPDs eligible to participate in PARHM, but that are not current PARHM participants in the RO Model (86 FR 42291).

The following is a summary of the public comments received on this proposal and our responses:

Comment: A few commenters supported our proposal to exclude from the RO Model only the HOPDs that are participating in PARHM, rather than excluding both HOPDs that are participating in PARHM and those that have been identified by CMS as eligible to participate in PARHM.

Response: We thank commenters for their support.

Comment: Some commenters opposed the inclusion in the RO Model of only HOPDs participating in PARHM, stating that they believe that participation in the RO Model should be voluntary, and thus no new PGPs or HOPDs, including HOPDs identified as eligible to participate in PARHM, should be required to participate in the RO Model.

Response: We did not solicit comments on mandatory participation under the RO Model in the CY 2022 OPPS/ASC proposed rule. We did, however, respond to comments requesting voluntary participation in the RO Model in the Specialty Care Models final rule. As discussed in the Specialty Care Models final rule, mandatory participation avoids the selection bias inherent to any model in which providers and suppliers may choose whether or not to participate (85 FR 61141). Such a design ensures sufficient proportional participation of both HOPDs and freestanding radiation therapy centers, which is necessary to obtain a diverse, representative sample of RT providers and RT suppliers that will allow a statistically robust test of the prospective episode payments made under the RO Model (85 FR 61141). Mandatory participation also facilitates a comparable evaluation comparison group (85 FR 61138). We therefore maintain, as we did in the Specialty Care Models final rule, that the mandatory design for the RO Model is necessary to enable CMS to detect change reliably in a generalizable sample of RT providers and RT suppliers to support a potential model expansion (85 FR 61138).

In terms of our proposal to include HOPDs that have been identified as eligible to participate in PARHM, but that are not actually participating in PARHM, in the RO Model, as we noted in the CY 2022 OPPS/ASC proposed rule, we no longer believe that including these hospitals in the RO Model will impact the PARHM evaluation because such HOPDs do not receive global budgets under PARHM, so including these hospitals in the RO Model would not result in an overlap between PARHM payments and RO Model payments. In addition, as described above, we now expect that the PARHM evaluation's comparison group will consist only of hospitals located outside of Pennsylvania. Thus, it is now our expectation that HOPDs that have been identified as eligible to participate in PARHM—all of which are located within the Commonwealth of Pennsylvania—would not be selected for the comparison group for the PARHM evaluation. Accordingly, we do not expect that including in the RO Model those HOPDs that have been identified as eligible to participate, but not actually participating in, PARHM would affect the ability to detect the impact of PARHM on the cost and quality of care.

In addition, as we stated in the proposed rule, while it remains the case that hospitals and CAHs may join

PARHM on an ongoing basis, hospitals and CAHs generally join PARHM at the start of a given CY. Because the RO Model's PYs would align with CYs, we stated in the CY 2022 OPPS/ACS proposed rule that we concluded it would be possible to update the RO Model exclusions for a given PY if an HOPD leaves or joins PARHM. In the CY 2022 OPPS/ACS proposed rule, we provided an example of a rural hospital identified as eligible to participate in PARHM that later initiates its participation in PARHM by signing a PARHM participation agreement with CMS (86 FR 42291). In the CY 2022 OPPS/ACS proposed rule, we inadvertently stated that the HOPDs participating in PARHM as part of that participating rural hospital would be excluded from participation in the RO Model as of the start of the next CY quarter that follows the date that the HOPD begins participating in PARHM. This statement was inaccurate. Rather, consistent with the exclusion from the RO Model of hospitals participating in PARHM, because these hospitals receive global budgets that would include payments for RT services and as such would overlap with the RO Model, we are clarifying that the HOPDs participating in PARHM as part of that participating rural hospital would be excluded from participation in the RO Model as of the start of the CY quarter that includes the HOPD's start date in PARHM. Specifically, to avoid overlapping participation between the RO Model and PARHM, in the rare circumstance that an HOPD begins its participation in PARHM on a date other than the first day of a CY quarter, that HOPD would be excluded from participation in the RO Model as of the start of the CY quarter when the HOPD joins PARHM—rather than as of the start of the following CY quarter. We similarly stated that, if an HOPD no longer participates in PARHM as part of a participating rural hospital, and the HOPD otherwise meets the definition of an RO participant, then the HOPD would be required to participate in the RO Model as of the start of the next CY quarter; we further clarify that, to avoid any overlap between the global budget payments and the RO Model payment, the HOPD would be required to participate in the RO Model as of the start of the CY quarter following the former PARHM participant's final global budget payment.

After considering public comments, we are finalizing the proposal to exclude only those HOPDs that are participating in the PARHM from the RO Model as opposed to all HOPDs that are eligible to participate in the PARHM. We are codifying this policy at our regulation at § 512.210(b)(5). As stated in the proposed rule (86 FR 42291), we will continue to use the list on the PARHM website at *https://innovation.cms.gov/initiatives/pa-ruralhealth-model/*, which is updated quarterly, to identify the hospitals that are participating in PARHM, and therefore identify the specific HOPDs excluded from participation in the RO Model.

We are further finalizing that HOPDs that are identified as eligible to participate in PARHM, but that are not current PARHM participants, will included in the RO Model if they are located in a CBSA selected for participation in the RO Model and that this exclusion of HOPDs associated with hospitals that participate in PARHM from the RO Model would apply only during the period of such participation. As previously described, if an HOPD begins its participation in PARHM on a date other than the first day of a CY quarter, that HOPD would be excluded from participation in the RO Model as of the start of the CY quarter when the HOPD joins PARHM, not of the start of the following CY quarter.

b. Community Health Access and Rural Transformation (CHART)

We also proposed to modify the exclusions from the RO Model at § 512.210(b)(6) so that the HOPD of any participating hospital in the Community Transformation Track of the Community Health Access and Rural Transformation (CHART) Model would be excluded from the RO Model. Specifically, for any CHART Community Transformation Track performance period during which a hospital is participating in the CHART Model, the HOPD would be excluded from the RO Model. We proposed to exclude these ''CHART HOPDs'' because these hospitals will receive prospective capitated payments, including HOPD-based RT services, that are not retrospectively reconciled based on experience during the CHART performance year, rather future payments are adjusted based on changes in population and proportion of services that participating HOPDs provide. We proposed to exclude CHART HOPDs to avoid double payment for the same services. The participating hospitals will be listed and updated on the CHART Model website at *https://innovation.cms.gov/innovation-models/chart-model*. For the CHART ACO Transformation Track, we proposed that we would follow the same policy for overlap between the RO Model and the Medicare Shared Savings Program ACOs, which was finalized at 85 FR 61260.

We solicited public comments on our proposal in section XVIII.C.3.B. of the CY 2022 OPPP/ASC proposed rule (86 FR 42291).

The following is a summary of the public comments received on this proposal and our responses:

Comment: We received some comments about the exclusion of HOPDs of any participating hospital in the Community Transformation Track of the CHART Model from the RO Model. All of these commenters supported this exclusion. A commenter also supported that for the CHART ACO Transformation Track we will follow the same policy for overlap between the RO Model and the Medicare Shared Savings Program ACOs, which is described at 85 FR 61260. A couple of commenters commented that exclusion from the RO Model of an HOPD of any participating hospital in the Community Transformation track of the CHART Model will have minimal impact, as 15 lead organizations will be selected for participation in the Community track CHART out of all specialties and it is unlikely that a radiation oncology practice would be selected to participate in CHART.

Response: We thank commenters for their support. We agree that the overlap between RO Model participants and participating hospitals in the Community Track of the CHART Model will be minimal. However, we need to account for any overlap that could potentially exist between the RO Model and CHART. We believe the best way to account for this overlap is to exclude HOPDs participating in the CHART Community Transformation track and for the CHART ACO Transformation track to follow the same policy that applies for overlap between the RO Model and the Medicare Shared Savings Program ACOs.

After considering public comments, we are finalizing as proposed to exclude HOPDs participating in the CHART Community Transformation track from the RO Model. We are codifying this policy at § 512.210(b)(6). We are clarifying in this final rule that HOPDs furnishing included RT services selected for participation in the CHART Community Transformation track will be RO participants in PY1 of the RO Model and are only excluded once the CHART Community Transformation track model performance period begins.

And, for the CHART ACO Transformation track, we are finalizing as proposed that we will follow the same policy for overlap as exists for overlap between the RO Model and the

Medicare Shared Savings Program ACOs.

c. Low Volume Opt-Out

We codified under § 512.210(c) that a PGP, freestanding radiation therapy center, or HOPD, which would otherwise be required to participate in the RO Model may choose to opt out of the RO Model for a given PY if it has fewer than 20 episodes of RT services across all CBSAs selected for participation in the most recent year with claims data available prior to the applicable PY. In the CY 2021 OPPS/ASC final rule (85 FR 86261), we amended this policy at § 512.210(c) to clarify the type of episodes used to determine eligibility for the low volume opt-out in each performance year, where episodes, as defined at § 512.205, are used to determine eligibility in PY1 and PY2 and RO episodes, as defined at § 512.205 and described at § 512.245(a), are used to determine eligibility in PY4 and PY5, and both episodes and RO episodes are used to determine eligibility in PY3. Specifically, for PY3, eligibility for the low volume opt-out is determined by counting episodes from January 1, 2021 through June 30, 2021 and RO episodes from July 1, 2021 through December 31, 2021. We codified at § 512.210(c)(6) that at least 30 days prior to the start of each PY, CMS will notify RO participants eligible for the low volume opt-out for the upcoming PY. If the eligible RO participant wishes to opt out, it must attest that it intends to do so prior to the start of the upcoming PY.

Because section 133 of the CAA, 2021 prohibits implementation of the RO Model prior to January 1, 2022, we proposed to modify the dates of the data used to determine eligibility for the low volume opt-out in the CY 2022 OPPS/ASC proposed rule to align with the requirements of the CAA, 2021. We proposed that a PGP, freestanding radiation therapy center, or HOPD, which would otherwise be required to participate in the RO Model may choose to opt out of the RO Model for a given PY if it has fewer than 20 episodes or RO episodes, as applicable, depending on the PY, across all CBSAs selected for participation in the most recent year with claims data available, which is 2 years prior to the applicable PY. We further proposed that episodes furnished prior to the start of the model performance period in CBSAs selected for participation will be used to determine the eligibility of the low volume opt-out for PY1 and PY2. If PY1 begins on January 1, RO episodes will be used to determine the eligibility of the low volume opt-out for PY3. If PY1 begins on any date other than January 1, both RO episodes of PY1 and episodes occurring in the CY of PY1 (but occurring prior to the start of PY1 in that year) in CBSAs selected for participation will be used to determine the eligibility of the low volume opt-out for PY3. RO episodes of PY2 and PY3 will be used to determine the eligibility of the low volume opt-out for PY4 through PY5, respectively.

We proposed definitions for legacy CCN and legacy TIN as follows. A legacy CCN means a CCN that an RO participant that is a hospital outpatient department, or its predecessor(s), previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services. We proposed that a legacy TIN means a TIN that an RO participant that is a PGP, or a freestanding radiation therapy center, or its predecessor(s), previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services.

We proposed to add at § 512.210(c)(7) that during the model performance period, an entity would not be eligible for the low volume opt-out if its legacy TIN or legacy CCN was used to bill Medicare for 20 or more episodes or RO episodes, as applicable, of RT services in the 2 years prior to the applicable PY across all CBSAs selected for participation.

We solicited public comments on the proposed definitions of legacy TIN and legacy CCN, as well as the proposal for how to address low volume opt-out eligibility in the case of an entity that has a change in TIN or CCN (86 FR 42291).

The following is a summary of the public comments received on these proposals and our responses:

Comment: One commenter requested clarification on how the low volume opt-out policy will be applied to completely new entities or for existing CCNs or TINs that add a radiation therapy service line. This commenter stated that CMS indicated in prior communications that such entities would not be eligible for the opt-out policy since they would have no historical claims to determine if they are eligible for the policy. This commenter asked CMS to establish a process by which new entities or entities adding a new service line that anticipate having low volume in the performance year could apply for the low volume opt-out.

A couple of the commenters noted that the low volume opt-out will not protect all small and rural facilities as many will not be eligible to opt out under this policy. These commenters stated that the RO Model's provisions may prove to be unexpectedly burdensome or financially infeasible for these RO participants. One commenter specifically disagreed with the threshold of fewer than 20 episodes or RO episodes, claiming that the threshold is exceedingly low and does not exempt radiation oncologists working less than half-time. This commenter explained that in small and rural counties, older adults (65+) make up a larger share of the population compared to urban and suburban areas, resulting in a large Medicare population to serve, thus making the 20-episode threshold impractical. This commenter suggested that a more realistic approach would be to use the low-volume threshold used in MIPS of 200 or fewer Medicare fee-for-service encounters.

One commenter recommended CMS allow RO participants to retrospectively request to opt out of a PY if it furnished fewer than 20 episodes in that PY. In this instance, an RO participant that retrospectively opts out would have its payments adjusted based on the FFS amount the RO participant would have been paid had it not been included in the RO Model.

Response: We thank these commenters for their comments. We finalized in the Specialty Care Models final rule (85 FR 61188) that a PGP, freestanding radiation therapy center, or HOPD which would otherwise be required to participate in the RO Model under § 512.210(c) may choose to opt-out of the RO Model on an annual basis if the PGP, freestanding radiation therapy center, or HOPD furnishes fewer than 20 episodes across all CBSAs selected for participation in the most recent calendar year with available claims data. We codified this policy at § 512.210(c) of that final rule.

As discussed in the Specialty Care Models final rule (85 FR 61188), the low volume opt-out option is intended to allow RO participants furnishing a small volume of RT services in the CBSAs selected for participation in the Model to opt out if they so choose, given the investment required to implement the RO Model versus the benefit of participating in the RO Model for a limited frequency of RT services. We note that prospective payments in general, including episode-based payment rates of the RO Model, are not designed to reflect specific investment decisions of individual RT providers and RT suppliers, such as practice-specific technology acquisition of new service lines.

We believe that requiring those RO participants eligible to opt-out of the RO Model to attest to the intention of opting

out of the RO Model prior to the start of the applicable PY (that is, on or before December 31 of the prior PY in which the opt-out would occur), and to do so before every PY for which the RO participant is eligible to opt out, is less disruptive to these RO participants than allowing them to opt out of the RO Model retrospectively. They can continue to bill and operate as they do under FFS without needing to meet additional RO Model requirements. Allowing RO participants to opt out of the RO Model retrospectively would be operationally complex. We also believe that it would not make sense to allow for RO participants to opt out retrospectively, since these RO participants would have prepared for the RO Model, billed RO episodes and carried out their requirements only to be paid under FFS for the few RO episodes they furnished.

In response to concerns from commenters concerning rural RT providers and RT suppliers, we did further analysis concerning the rural and urban landscape of the ZIP Codes linked to CBSAs selected for participation in the Model. We used the U.S. Department of Agriculture's Economic Research Service's ''2010 Rural-Urban Commuting Area (RUCA) Code, ZIP Code file'' last updated in August 2020 (*https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx*) to analyze the population density, urbanization, and daily commuting patterns of the RO Model's participating ZIP Codes that are linked to CBSAs selected to participate in the RO Model. The Primary RUCA classification contains whole numbers (1–10) to delineate metropolitan, micropolitan, small town, and rural commuting areas based on the size and direction of the primary (largest) commuting flows, where RUCA category 1 is highly urban and RUCA category 10 is highly rural. RUCA category 1 is described in the ZIP Code file as having a metropolitan area core with primary flow within an urbanized area. RUCA category 10 is described in the code file as having a primary flow to a tract outside an urbanized area or urban cluster. RUCA category 4 is defined as having a micropolitan area core with primary flow within a large urban cluster of 10,000 to 49,999.

Among RT providers and RT suppliers eligible to participate in the RO Model, we found that approximately 98 percent of their 2020 episodes furnished in participating ZIP Codes were furnished in RUCA categories classified as 1 and 4, with approximately 85 percent in RUCA category 1 and 13 percent in RUCA category 4. We found that approximately less than 2 percent of 2020 episodes furnished in participating ZIP Codes were furnished by those RT providers or RT suppliers billing in RUCA category classified as 2. No 2020 episodes were furnished in participating ZIP Codes by those RT providers or RT suppliers in RUCA category classified as 3. Less than 1 percent of 2020 episodes furnished in participating ZIP Codes were furnished by RT providers or RT suppliers billing in RUCA categories classified as 5 through 10.

We then examined the range of the combined adjustments, reflecting the RO participant's historical experience and case mix values, for both the PC and TC based on our proposed policies where the historical experience and case mix adjustments for PY1 would be based on 2017–2019 episodes. We found similar patterns of adjustment values across those RT providers and RT suppliers in RUCA category 1 and 4. Although we also found similar patterns of adjustment values across RT providers and RT suppliers furnishing episodes in the remaining RUCA categories, the number of those RT providers and RT suppliers and their corresponding episodes in the other RUCA categories are too small to draw reliable conclusions. We uncovered no evidence that rural providers have sufficiently different patterns of adjustment values than non-rural providers to indicate participation in the RO Model may be burdensome or financially infeasible for RO participants that furnish RT care in rural areas such that a change in our low volume opt-out policy specific to rural areas is warranted. We also note that any RO participant, regardless of the RUCA category within which they are furnishing RO episodes, can opt out of the RO Model if they are so eligible due to low volume.

As we stated in the Specialty Care Models final rule (85 FR 61147), we believe that allowing entities with fewer than 20 episodes to opt-out achieves the right balance of allowing very small entities to opt-out if they believe the burden from participation in the RO Model would outweigh the possibility of benefits from model participation (for example, potential for care improvements or increased payments), while also maintaining a variety of RO participant types in the RO Model to promote generalizability (to the extent possible) of any impact results. We do not believe it is necessary to allow RO participants adding new service lines to choose to opt out of the RO Model for a given PY if it has fewer than 20 episodes of RT services across all CBSAs selected for participation in the most recent year with claims data available prior to the applicable PY. The trend factor will reflect updates to input prices as reflected in updated PFS and OPPS rates. As we stated in the Specialty Care Models final rule (85 FR 61188), prospective payments in general, including episode-based payment rates of the RO Model, are not designed to reflect specific investment decisions of individual providers and suppliers. We do not currently classify episodes based on whether they are related to an existing service line or a service line that was not furnished and billed by the RO participant historically, and therefore, whether an RO participant has added a new service line or not is not relevant to our payment methodology or low volume opt-out policy. We did note in the Specialty Care Models final rule (85 FR 61188) that we may consider revising this policy in the future.

Please note that any new TIN or new CCN, regardless of whether it is result of a merger, acquisition, or other business relationship, must opt out of a PY prior to the start of that PY, if it is so eligible. If a PGP, freestanding radiation therapy center, or HOPD begins furnishing included RT services in a CBSA selected for participation in the RO Model during a PY, that entity would be unable to opt out of the PY that is currently underway.

After considering public comments, we are finalizing as proposed that a PGP, freestanding radiation therapy center, or HOPD, which would otherwise be required to participate in the RO Model may choose to opt out of the RO Model for a given PY if it has fewer than 20 episodes or RO episodes, as applicable, depending on the PY, across all CBSAs selected for participation in the most recent year with claims data available, which is 2 years prior to the applicable PY. We are finalizing that episodes furnished prior to the start of the model performance period in CBSAs selected for participation will be used to determine the eligibility of the low volume opt-out for PY1 and PY2. If PY1 begins on January 1, RO episodes will be used to determine the eligibility of the low volume opt-out for PY3. If PY1 begins on any date other than January 1, both RO episodes of PY1 and episodes occurring in the CY of PY1 (but occurring prior to the start of PY1 in that year) in CBSAs selected for participation will be used to determine the eligibility of the low volume opt-out for PY3. RO episodes of PY2 and PY3 will be used to determine the eligibility of the low volume opt-out for PY4 and

PY5, respectively. We are codifying this policy at our regulation at § 512.210(c).

We received no comments on the definitions of legacy TIN and legacy CCN, and therefore we are finalizing these definitions at § 512.205 with one technical change to the proposed definition of legacy CCN. We are changing ''radiotherapy services'' to ''RT services'' because that is the defined term in the regulations. After considering public comments, we are also finalizing the policy that CMS will include episodes and RO episodes, as applicable, associated with the RO participant's current CCN or TIN and episodes and RO episodes, as applicable, attributed to the RO participant's legacy CCN(s) or legacy TIN(s), in determining whether the participant is eligible for the low volume opt out. We are finalizing as proposed that an entity will not be eligible for the low volume opt-out if its legacy TIN or legacy CCN was used to bill Medicare for 20 or more episodes or RO episodes, as applicable, of RT services in the 2 years prior to the applicable PY across all CBSAs selected for participation. We are codifying these definitions and this policy at our regulation at § 512.205 and § 512.210(c)(7) respectively.

4. Certain Changes to RO Model Episodes

a. Criteria for Determining Included Cancer Types

The criteria for cancer types to be included in the RO Model are set forth at § 512.230(a). CMS proposed to reorganize § 512.230(a) and (b) to improve the clarity and internal consistency of the regulatory text. We proposed to amend § 512.230(a) and (b) such that to be included in the RO Model, a cancer type must be commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines; associated with current ICD–10 codes that have demonstrated pricing stability, which is determined by analyzing the interquartile ranges of the episode prices across cancer types as described in the Specialty Care Models final rule at 85 FR 61155; and the Secretary must not have determined that the cancer type is not suitable for inclusion in the RO Model. We proposed that CMS would remove from the RO Model a cancer type that does not meet all three of these criteria or for which CMS discovers a greater than 10 percent error in the established national base rates.

Comment: We received a few comments in support of the RO Model's current policy, including support for including radiation therapy treatments that are commonly used for multiple cancer types. A few commenters noted that the list of included cancer types is still too broad and CMS should limit the number of cancers to those cancers where there is strong clinical evidence for a range of treatment alternatives, such as prostate cancer, breast cancer, and lung cancer. We received a comment expressing support for including only cancer types with evidence of effective use of hypofractionation to ensure delivery of clinically appropriate care and value. A separate commenter asked that CMS reduce the 15 cancer types to a smaller number for the initial rollout of the RO Model.

Response: We appreciate the comments. We note that we did not propose any substantive changes to our policy that determines what cancer types are included in the RO Model, but instead simply reorganized the content in § 512.230(a) and (b). The included cancer types are determined by the following criteria as stated in the proposed reorganization for § 512.230(a): All are commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines; all cancer types have one or more associated current ICD–10 codes that have demonstrated pricing stability; and the Secretary has not determined that the cancer type is not suitable for inclusion.

As we noted at 85 FR 61157, the cancer types that are included in the RO Model are cancers commonly treated with RT, and we exclude those cancers that are rarely treated with radiation. CMS believes that limiting or phasing in the number of included cancer types would be more burdensome for most RO participants. For most RO participants, limiting or phasing in cancer types would mean that the RO Model requirements and billing guidance would apply to a subset of their RT services rather than to than to the majority of their RT services for a significant portion of the model performance period (or if cancer types were further limited, for the entire model performance period).

Further, as we stated in the Specialty Care Models final rule at 85 FR 61157, CMS believes that phasing in the included cancer types would prevent a robust evaluation because doing so would reduce the amount of available data for any cancer types phased in at a later time. We believe that a model performance period of at least 5 years is sufficient to obtain data to compute a reliable impact estimate.

As we stated in the Specialty Care Models final rule at 85 FR 61156, the RO Model is designed to be disease-specific and agnostic to treatment and modality type. That is, we do not require that multiple treatment alternatives exist for a given cancer type, or that hypofractionation be an option for treating the cancer type, to be included in the RO Model because the purpose of the RO Model is to test an episode-based payment that is not specific to how many treatments or which modalities are furnished, which would retain FFS incentives. Rather than these types of requirements, our criteria for the included cancer types includes the requirement that each cancer type demonstrate pricing stability. As we described in the Specialty Care Models final rule at 85 FR 61157, although individual episodes may deviate from the average number of fractions for the cancer type (depending on the clinical profile of the individual patient), we have determined that all of the included cancer types have pricing stability, which allows them to be accurately priced to support the RO Model test.

We will continue to review whether the included cancer types meet the criteria at § 512.230. As we recently did with liver cancer, we will update the included cancer types as is detailed in § 512.230 when a cancer type needs to be added to the RO Model or excluded from the RO Model.

Comment: We received one comment in which the commenter expressed concern about the inclusion of bone and brain metastases because the treatments of both cancers can vary widely in the approach and technology used depending on the specific patient and disease progression.

Response: We appreciate this comment. CMS has determined that brain and bone metastases meet all three criteria for inclusion. As we stated in the Specialty Care Models final rule (85 FR 61188), we believe that treatment patterns as reflected in the episode file represent the variation in care patterns currently delivered nationally for all included cancer types. The case mix model incorporates cancer type and so the participant-specific case mix adjustment for the PC and/or the TC of the RO Models reflects the case mix of the RO participant's population, including those with bone and brain metastases. The same is true for the approach taken for the historical experience adjustment.

We are finalizing our proposal to reorganize our regulations at § 512.230(a) and (b) without modification.

b. Removal of Liver Cancer From Included Cancer Types

In section XVIII.C.4.b. of the CY 2022 OPPS/ASC proposed rule we stated that liver cancer met the criteria for exclusion set forth in regulatory language in § 512.230(a) and (b), regulatory text that we also proposed to reorganize as described above. While we did not request comment on removing liver cancer from the RO Model, we received supportive comments related to removing liver cancer from the list of included cancer types. See Table 74 below, for the current list of included cancer types.

BILLING CODE 4120–01–P

TABLE 74: Included Cancer Types and Corresponding ICD-10 Codes

Cancer Type	ICD-10 Codes
Anal Cancer	C21.xx
Bladder Cancer	C67.xx
Bone Metastases	C79.51
Brain Metastases	C79.3x
Breast Cancer	C50.xx, D05.xx
Cervical Cancer	C53.xx
CNS Tumors	C70.xx, C71.xx, C72.xx
Colorectal Cancer	C18.xx, C19.xx, C20.xx
Head and Neck Cancer	C00.xx, C01.xx, C02.xx, C03.xx, C04.xx, C05.xx, C06.xx, C07.xx, C08.xx, C09.xx, C10.xx, C11.xx, C12.xx, C13.xx, C14.xx, C30.xx, C31.xx, C32.xx, C76.0x
Lung Cancer	C33.xx, C34.xx, C39.xx, C45.xx
Lymphoma	C81.xx, C82.xx, C83.xx, C84.xx, C85.xx, C86.xx, C88.xx, C91.4x
Pancreatic Cancer	C25.xx
Prostate Cancer	C61.xx
Upper GI Cancer	C15.xx, C16.xx, C17.xx
Uterine Cancer	C54.xx, C55.xx

BILLING CODE 4120–01–C

c. Removal of Brachytherapy From Included RT Services

We codified at § 512.240 the modalities that are included under the RO Model: 3-dimensional conformal radiotherapy (3DCRT), intensity-modulated radiotherapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT), proton beam therapy (PBT), image-guided radiation therapy (IGRT), and brachytherapy. We proposed to amend § 512.240 to remove brachytherapy as an included modality in the RO Model.

We finalized a waiver of section 1833(t)(2)(H) of the Act under the authority of section 1115A(d)(1) of the Act, because it was necessary for the purposes of testing the RO Model when we were including brachytherapy as part of the RO Model, as discussed in the Specialty Care Models final rule at 85 FR 61242 and codified at § 512.280(f)(4). Given that our proposal to remove brachytherapy from the RO Model, if finalized, would render our waiver of section 1833(t)(2)(H) of the Act moot, we proposed to withdraw this waiver if our proposal to remove brachytherapy is finalized as proposed, because it would no longer be necessary solely for the purposes of testing the RO Model.

We solicited public comments on our proposal in section XVIII.C.4.c. of the CY 2022 OPPS/ASC proposed rule (86 FR 42293).

The following is a summary of the public comments received on this proposal and our responses:

Comment: CMS received many comments in support of the proposed policy to remove brachytherapy from the RO Model's list of included modalities; no commenters opposed removing brachytherapy. One commenter noted that the removal of brachytherapy will significantly lessen the number of RO Model claims that will be incorrectly paid. Another commenter supported removal because of the frequency in which brachytherapy is being furnished at PPS-exempt hospitals. One commenter noted that historically, brachytherapy has been under-reimbursed compared to other forms of radiotherapy, and its utilization in the United States has declined in recent years, and that this trend has not been observed in other countries. This commenter supported the potential for including brachytherapy services in future iterations of the RO Model. A couple commenters asked that CMS work with stakeholders to find a way to include brachytherapy in later model performance periods.

A few commenters stated that they did not support including brachytherapy within the RO Model's bundled payment in the future. One commenter did not support including brachytherapy during the model performance period given the commenter's perception that the RO Model's pricing and payment mechanism are complex. This commenter opposed inclusion because it would increase the Model's complexity.

One commenter stated that brachytherapy sources are vastly different than other included modalities. This commenter stated that brachytherapy sources are more similar to drugs and radiopharmaceuticals that are also excluded from the bundled payments under the RO Model. This commenter also stated that external beam radiation often requires less variation in resource use among patients with similar types of cancer who are treated by the same radiation oncology provider than do those who receive brachytherapy treatment. A couple commenters supported the removal of brachytherapy because they did not believe the episode payments adequately covered brachytherapy sources, pointing to low dose rate brachytherapy sources such as Cesium-131 as an example.

Some commenters supporting the brachytherapy exclusion stated their belief that the RO pricing methodology is insufficient for multimodality episodes, such as those that include brachytherapy. Many of these commenters noted that although they are supportive of the proposal to remove brachytherapy, it does not address what commenters perceived to be the inadequate payment for brachytherapy services under FFS Medicare, which they argued has created access to care issues for this particular modality for years.

Response: We appreciate the feedback. CMS seeks to neither incentivize nor discourage the use of one modality over another, but rather to encourage RT providers and RT suppliers to choose RT services that are the most clinically appropriate for RO beneficiaries under their care. The exclusion of a modality from the RO Model is not meant to imply anything about the value of such modality. Published clinical evidence suggests brachytherapy is a high-value RT service, which could warrant its inclusion in the RO Model. However, we acknowledge the concerns stakeholders have about possible unintended consequences for beneficiaries' access to care were brachytherapy to remain in the RO Model under the existing pricing methodology.

We note that we are not responding at this time to comments related to how we might include brachytherapy as a single modality or as multimodality episodes in the future. We are also not addressing comments about the perceived inadequate payment for brachytherapy services under FFS Medicare. We appreciate these comments and will consider them in future rulemaking.

Comment: Many commenters noted that if CMS finalizes the removal of brachytherapy, we should consider removing the incorrect payment withhold from the RO Model's pricing methodology. These commenters argued that without brachytherapy in the RO Model, this withhold is unnecessary.

Response: There are additional payment scenarios (such as incomplete episodes and duplicate services) beyond a multimodality episode with brachytherapy that require reconciliation and payment from the incorrect payment withhold. Therefore, we are not removing the incorrect payment withhold from the RO Model's pricing methodology.

Comment: We received a few comments in support of withdrawing our waiver of section 1833(t)(2)(H) of the Act in § 512.280(f)(4). A few commenters urged CMS to continue to uphold the safeguards that Congress established for paying for brachytherapy sources under the hospital OPPS under section 1833(t)(2)(H) of the Act and refrain from waiving the safeguards in the future.

Response: We thank commenters for their support.

We are finalizing the removal of brachytherapy from the list of included modalities in the RO Model codified at § 512.240 and are amending § 512.280(f)(4) to remove 1833(t)(2)(H).

d. Exclusion of IORT

We finalized in the Specialty Care Models final rule (85 FR 61114) that IORT would not be included as a modality in the RO Model. We asked for comments on how we might include IORT in future years at XVIII.C.4.d. of the CY 2022 OPPS/ASC proposed rule and we noted at 86 FR 42296 that we did not intend to respond to these comments in this final rule. We received some comments related to this issue and appreciate these comments. We will consider these comments in future rulemaking.

5. Pricing Methodology

a. Assignment of Cancer Types to an Episode

We finalized at 85 FR 61179 our process for assigning a cancer type to an episode as follows: First, we identify ICD–10 diagnosis codes during an episode from: (1) Medicare PFS claims for evaluation and management (E&M) services with an included cancer diagnosis code with a date of service during the 30 days before the episode start date, on the episode start date, or during the 29 days after the episode start date; and (2) Medicare PFS claims for treatment planning and delivery services with an included cancer diagnosis code (See Table 57), or Medicare OPPS claims for treatment delivery services with an included cancer diagnosis code on the claim header, with a date of service on the episode start date or during the 29 days after the episode start date. The cancer diagnosis code from OPPS claims must be the principal diagnosis to count toward cancer type assignment, and treatment delivery services that concern image guidance do not count toward cancer type assignment as we determined that image guidance was not an important indicator of cancer type. Then, we analyze and count these ICD–10 diagnosis codes across the claim lines to determine the episode's cancer type assignment according to the algorithm described in (1) through (3):

(1) If two or more claim lines fall within brain metastases or bone

metastases or secondary malignancies (per the mapping of ICD–10 diagnosis code to cancer type described in Table 57 of Identified Cancer Types and Corresponding ICD–10 Codes), we set the episode cancer type to the type (either brain metastases or bone metastases) with the highest count. If the count is tied, we assign the episode in the following order of precedence: Brain metastases; bone metastases; other secondary malignancies.

(2) If there are fewer than two claim lines for brain metastases, bone metastases or other secondary malignancies, we assign the episode the cancer type with the highest claim line count among all other cancer types. We exclude the episode if the cancer type with the highest claims line count among other cancer types is not an included cancer type.

(3) If there are no claim lines with a cancer diagnosis meeting the previously discussed criteria, then no cancer type is assigned to that episode and therefore, that episode is excluded from the national base rate calculations.

Since the publication of the Specialty Care Models final rule, a stakeholder has asked for clarification on how to identify when there are fewer than two claim lines for brain metastases, bone metastases or other secondary malignancies. In response to the stakeholder's request, in the proposed rule, we clarified paragraph (2) at 86 FR 42296. Specifically, if there are not at least two claim lines for brain metastases or at least two claim lines for bone metastases or at least two claim lines for any other secondary malignancy, then we assign the episode the cancer type with the highest line count among all other cancer types. For example, one bone metastases claim line and one secondary metastasis claim line will not qualify as two or more claim lines that fall within brain metastases or bone metastases or secondary malignancies. Instead, the episode will be assigned whatever cancer type had the highest line count among all other cancers.

We clarified in the CY 2022 OPPS/ASC proposed rule that we use a broad list of cancer diagnoses (those included in the RO Model and those not included) to assign cancer type to episodes in the baseline period. This broad list of cancer diagnoses is posted on the RO Model website at *https://innovation.cms.gov/innovationmodels/radiation-oncology-model*. We identify ICD–10 diagnosis codes for cancer during an episode from E&M services, and treatment planning and delivery services that have a cancer diagnosis code from that broad cancer diagnosis list. We assign a cancer type to the episode as described in this proposed rule. We then exclude those episodes that are not assigned an included cancer type. We do not exclude claims of excluded cancer types prior to episode construction, as this could lead to an episode being included in the RO Model where most of the RT services were related to treating an excluded cancer type.

We did not solicit public comments on this clarification in section XVIII.C.5.a. of the CY 2022 OPPS/ASC proposed rule (86 FR 42296).

b. Constructing Episodes Using Medicare FFS Claims and Calculation of Episode Payment

We proposed to update how we describe our pricing methodology. We proposed to remove references to specific CYs from the definition of baseline period, but we would still construct episodes based on dates of service for Medicare FFS claims paid during the baseline period as well as claims that are included under an episode where the initial treatment planning service occurred during the baseline period. Furthermore, although we proposed to remove references to specific CYs, we would continue to weigh the most recent observations more heavily than those that occurred in earlier years, as previously finalized. We would continue to weigh episodes that initiated in the first year of the baseline period at 20 percent, episodes that initiated in second year of the baseline period at 30 percent, and episodes that initiated in the third year of the baseline period at 50 percent. We invited comment on the proposal to weigh the most recent episodes more heavily than those that occurred in earlier years in the baseline period. We solicited public comments on our proposal in section XVIII.C.5.b. of the CY 2022 OPPS/ASC proposed rule (86 FR 42297).

The following is a summary of the public comments received on this proposal and our responses:

Comment: A couple of commenters agreed with CMS's proposed policy to weigh the most recent episodes more heavily than those that occurred in earlier years in the baseline. One of those commenters added that this weighting scheme is appropriately balanced giving more weight to the most recent data while using multiple years in the baseline period provides year-to-year stability.

Response: We thank these commenters for their support.

After considering public comments, we are finalizing as proposed to weigh the most recent episodes more heavily than those that occurred in earlier years in the baseline period. We received no comments on our proposed modification to the definition of baseline period, and therefore, we are also finalizing as the definition of baseline period without modification and codifying the definition at § 512.205.

We codified at § 512.255(c)(13) that for sequestration, we deduct 2 percent from each episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, discount, withholds, and coinsurance to the national base rate. At times, the requirements for sequestrations are modified by legislation or regulation. For example, section 3709(a) of division A of the Coronavirus Aid, Relief and Economic Security (CARES) Act (Pub. L. 116–136) included a temporary moratorium on sequestration for all Medicare programs beginning on May 1, 2020 and ending on December 31, 2020, while section 102(a) of division N of the CAA, 2021 (Pub. L. 116–260), extended the suspension period to March 31, 2021. An Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes (Pub. L. 117–7), signed into law on April 14, 2021, extends the suspension period to December 31, 2021. Thus, we proposed to amend § 512.255(c)(13) by removing the percentage amount and indicating that sequestration will be applied in accordance with applicable law.

We solicited public comments on our proposal in section XVIII.C.5.b of the CY 2022 OPPS/ASC proposed rule (86 FR 42298).

The following is a summary of the public comments received on this proposal and our responses:

Comment: A couple of commenters all supported removing the specific reference to the sequestration percentage amount and changing text language to indicate that the exact amount will be determined in accordance with the applicable current law.

Response: We thank these commenters for their support.

After considering public comments, we are finalizing our proposal to amend § 512.255(c)(13) by removing the percentage amount and indicating that sequestration will be applied in accordance with applicable law. We are also codifying these policies at § 512.255(c)(13).

c. National Base Rates

We codified at § 512.250(b) the criteria for excluding episodes, as more fully described in 85 FR 61183 through

61184. We finalized that we would exclude episodes in the baseline (finalized in this rule to be formally defined as ''baseline period'') that are not attributed to an RT provider or RT supplier. These episodes are exceedingly rare. There were fewer than 15 episodes out of more than 518,000 episodes in the 2016 to 2018 period where the only RT delivery services in the episode were classified as professional services. There are a few brachytherapy surgery services that are categorized as professional services. We also finalized that episodes would be excluded if either the PC or TC is attributed to an RT provider or RT supplier with a U.S. Territory service location or to a PPS-exempt entity, but that services within an episode provided in a U.S. Territory or provided by a PPS-exempt entity would be included in the episode pricing. We finalized that episodes would be excluded if they include any RT service furnished by a CAH. Finally, we finalized that we would exclude all Maryland and Vermont claims before episodes are constructed and attributed to an RT provider or RT supplier, and we would similarly exclude inpatient and ASC claims from episode construction and attribution. We finalized a policy that excluded claims before episodes were constructed in certain cases, while in other cases, we excluded entire episodes after construction if they included claims that were to be excluded.

To simplify episode construction, attribution, and pricing, we proposed to exclude all Maryland, Vermont, and U.S. Territory claims and all CAH, inpatient, ASC, and PPS-exempt claims in the same manner: before episodes are constructed and attributed to an RT provider or RT supplier. Furthermore, to mirror the participant exclusion policy proposed in section XVIII.C.3. of the CY 2022 OPPS/ASC proposed rule, we proposed to exclude all claims of an HOPD participating in PARHM (during the time period of their participation in PARHM) before episodes are constructed and attributed to an RT provider or RT supplier. We also clarified that we will exclude episodes from the RO Model's pricing methodology that are attributed to an RT provider or RT supplier that is located in a ZIP Code not assigned to a CBSA, not assigned an included cancer type, or that do not have more than $0 in total allowed amount for professional or technical services from Model pricing. We proposed to amend § 512.250(b) accordingly.We solicited public comments on our proposal in section XVIII.C.5.c. of the CY 2022 OPPS/ASC proposed rule (86 FR 42298).

The following is a summary of the public comments received on this proposal and our response:

Comment: We received no comments on the proposal to exclude all Maryland, Vermont, and U.S. Territory claims and all CAH, inpatient, ASC, and PPS-exempt claims in the same manner: before episodes are constructed and attributed to an RT provider or RT supplier. We received comments concerning the inclusion of HOPDs identified as eligible to participate in PARHM, which we summarized and responded to in section XVII.C.3.a of this final rule with comment period, but we received no comments specifically related to PARHM considerations in episode construction.

Response: After considering public comments, we are finalizing our proposal to exclude all Maryland, Vermont, and U.S. Territory claims and all CAH, inpatient, ASC, and PPS-exempt claims before episodes are constructed and attributed to an RT provider or RT supplier. We are also finalizing the proposal to exclude all claims of an HOPD participating in PARHM (during the time period of their participation in PARHM) before episodes are constructed and attributed to an RT provider or RT supplier.

We proposed to define the baseline period as the 3-year period within which episodes must initiate in order to be used in the calculation of the national base rates, participant-specific professional and technical historical experience adjustments, and participant-specific professional and technical case mix adjustments for PY1. We proposed that the baseline period would be January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in CY 2022, in which case the baseline period will would be adjusted according to the new model performance period (that is, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).

Comment: A couple commenters expressed concern about how we will handle episode data from CYs 2020 and 2021 in the RO Model given the COVID–19 PHE. One commenter noted that because we proposed that the historical experience adjustment be based on 2017–2019 data which would stay constant throughout the duration of the model performance period, the additional cost associated with delivering more expensive treatment for advanced disease due to the COVID–19 PHE would not be captured in that component of the pricing methodology. One commenter supported this 2017–2019 baseline period, specifically because it does not include 2020. The commenter argued that the pandemic depressed healthcare utilization including essential treatment for conditions such as cancer in ways that are not representative of best practices outside of a pandemic.

Response: We thank these commenters for stating their concerns. Please reference the RO Model's EUC policy in section XVII.C.10. of this final rule with comment period for discussion about the pricing methodology and how specific episode data may be handled should an EUC policy be invoked. We are finalizing our policy that the baseline period will be defined as the three calendar year period that begins on January 1 no fewer than five years but no more than six years prior to the start of the model performance period during which episodes must initiate in order to be used in the calculation of the national base rates, each RO participant's historical experience adjustment for the PC or TC or both for the model performance period, and the RO participant's case mix adjustment for the PC or TC or both for PY1. We are finalizing that the baseline period is January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in CY 2022. Our finalized national base rates for the model performance period are based on the criteria set forth for cancer type inclusion and are summarized in Table 75 of this final rule with comment period.

BILLING CODE 4120–01–P

TABLE 75: National Base Rates

RO Model-Specific Codes	Professional or Technical	Included Cancer Type	National Base Rate
M1072	Professional	Anal Cancer	$3,104.11
M1073	Technical	Anal Cancer	$16,800.83
M1074	Professional	Bladder Cancer	$2,787.24
M1075	Technical	Bladder Cancer	$13,556.06
M1076	Professional	Bone Metastases	$1,446.41
M1077	Technical	Bone Metastases	$6,194.22
M1078	Professional	Brain Metastases	$1,651.56
M1079	Technical	Brain Metastases	$9,879.40
M1080	Professional	Breast Cancer	$2,059.59
M1081	Technical	Breast Cancer	$10,001.84
M1084	Professional	CNS Tumor	$2,558.46
M1085	Technical	CNS Tumor	$14,762.37
M1082	Professional	Cervical Cancer	$3,037.12
M1083	Technical	Cervical Cancer	$13,560.15
M1086	Professional	Colorectal Cancer	$2,508.30
M1087	Technical	Colorectal Cancer	$12,200.62
M1088	Professional	Head and Neck Cancer	$3,107.95
M1089	Technical	Head and Neck Cancer	$17,497.16
M1094	Professional	Lung Cancer	$2,231.40
M1095	Technical	Lung Cancer	$12,142.39
M1096	Professional	Lymphoma	$1,724.07
M1097	Technical	Lymphoma	$7,951.09
M1098	Professional	Pancreatic Cancer	$2,480.83
M1099	Technical	Pancreatic Cancer	$13,636.95
M1100	Professional	Prostate Cancer	$3,378.09
M1101	Technical	Prostate Cancer	$20,415.97
M1102	Professional	Upper GI Cancer	$2,666.79
M1103	Technical	Upper GI Cancer	$14,622.66
M1104	Professional	Uterine Cancer	$2,737.11
M1105	Technical	Uterine Cancer	$14,156.20

BILLING CODE 4120–01–C

d. Trend Factors

We codified our policy at § 512.255(c)(1) to apply a trend factor (an adjustment applied to the national base rates that updates those rates to reflect current trends in the OPPS and PFS rates for RT services) to each of the national base rates. In the Specialty Care Models final rule at 85 FR 61186, we stated that for each PY, we will calculate separate trend factors for the PC and TC of each cancer type using data from HOPDs and freestanding radiation therapy centers not participating in the RO Model. Each of the separate trend factors will be updated and applied to the national base rates prior to the start of each PY (for which they would apply) so as to account for trends in payment rates and volume for RT services outside of the RO Model under OPPS and PFS. We clarified in the CY 2022 OPPS/ASC proposed rule at 86 FR 42299 through 42300, that the number of separate trend factors will vary depending on the number of cancer types included in the RO Model.

Given the multiple delays in the model performance period and our proposal to update the baseline period, we proposed that the numerator of the trend factor would be the product of (a) the average number of times each

HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished 3 years prior to the CY used to determine the FFS payment rates and (b) the component's FFS payment rate (as paid under OPPS or PFS) for the CY of the upcoming PY. We proposed that the denominator of the trend factor would be the product of (a) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished in the most recent year of the baseline period and (b) the corresponding FFS payment rate for the most recent year of the baseline period. We also clarified that the trended national base rates will be made available on the RO Model website prior to the start of the applicable PY, along with this final rule.

We solicited public comments on our proposals in section XVIII.C.5.d. of the CY 2022 OPPS/ASC proposed rule (86 FR 42300).

The following is a summary of the public comments received on the proposal to base the denominator of the trend factor on the third year of the proposed baseline period, and the numerator of the trend factor on FFS payment rates for the same CY as the upcoming PY combined with utilization from the third year of the baseline period for PY1, the first CY after the baseline period for PY2, the second CY after the baseline period for PY3, and so on, and our response:

Comment: Many commenters disagreed with the proposed modification of the trend factor, because it did not include guardrails to prevent significant shifts in payment rates under the RO Model's trend factors, since the trend factor methodology incorporates the MPFS and OPPS rates as part of an annual update for the PC and TC of each disease site. These commenters argued that without the guardrails, the proposed trend factor methodology limits rate stability if MPFS and OPPS experience significant payment shifts from year-to-year. Many of these commenters recommended a guardrail of +/-2 percent to help establish rate stability. One commenter argued that it was inappropriate to apply, in part, the rate of growth in physician payments to payments for RT services furnished in HOPDs, as CMS intends to do under the RO Model. This commenter argued that when Congress passed MACRA, it did not intend to apply the annual PFS update factor of 0 percent to payments made under OPPS for the years 2020 through 2025. This commenter recommended that CMS calculate one trend factor for the technical component of RT services furnished in the freestanding radiation therapy center setting using the change in PFS payments and one for the technical component of RT services furnished in an HOPD setting using the change in OPPS payments.

Another commenter argued it will likely take several years before new technology or treatments are reflected in sufficient volume to impact and be reflected in the FFS rates, and, as a result, CMS should establish an add-on payment to account for new technologies.

Many commenters stated that not having access to trend factor values coupled with not having access to participant-specific case mix and historical experience adjustment values until two months prior to the start of the model performance period prevented them from having the critical data they needed to assess the financial implications of the RO Model.

Response: We thank these commenters for their comments. We note that modifications in this section involve the removal of references to specific years, and, instead, add references to specific periods of time relative to the baseline period or upcoming PY. For example, instead of stating a specific year like ''2019,'' we now state ''3 years prior to the CY used to determine the FFS payment rates.'' This allows the text to remain current even if there is a change in baseline period or model performance period.

As we stated in the Specialty Care Models final rule (85 FR 61188), we believe the best way to calculate the trend factors such that spending under the RO Model does not diverge too far from spending under FFS Medicare that non-participants will receive for the underlying bundle of included RT services had they been in the RO Model, is to base the trend factors on service volumes from episodes attributed to both HOPDs and freestanding radiation therapy centers, and on updated PFS and OPPS rates. Calculating unique trend factors for the PC and TC for each cancer type and separately for those furnished in the HOPD setting from those furnished in the freestanding radiation therapy center setting works against the RO Model's goal of site neutrality. As we stated in the Specialty Care Models final rule (85 FR 61188), the trend factors will only generate significant swings if there are large swings in payment rates for RT services that are frequently used during episodes. CMS believes that setting up guardrails risks paying significantly more under the Model than to non-participants. Moreover, to the extent that new technologies and new equipment are billed under new HCPCS codes, we would go through rulemaking to add those new codes to the list of included RT services as we stated at 85 FR 61165.

Since the numerator of the trend factor is based, in part, on each component's (PC or TC) FFS payment rate (as paid under OPPS or PFS) for the CY of the upcoming PY, it is not possible to post trended national base rates prior to when those FFS payment rates are finalized in November prior to the upcoming PY. Please note that we will monitor the adequacy of payments over time, including the trend factor, and consider re-baselining in a later PY if our analysis indicates it is appropriate. Although it may be inferred from the description of the trend factor calculation, we would also like to clearly state that the accounting of ''the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished'' as described in the numerator and denominator, is by episode.

We are finalizing our policies as proposed, that is, we will base the denominator of the trend factor on the third year of the baseline period and the numerator of the trend factor on FFS payment rates for the same CY as the upcoming PY combined with utilization from the third year of the baseline period for PY1, the first CY after the baseline period for PY2, the second CY after the baseline period for PY3, and so on.

e. Applying the Adjustments

We finalized our policy at 85 FR 61194 that the combined adjustment, that is the adjustment that results when the corresponding participant-specific historical experience and case mix adjustments, and blend are combined, will be multiplied by the corresponding trended national base rate from Step 2 for each included cancer type. We will repeat this calculation for the corresponding case mix adjustment, historical experience adjustment, and blend for the TC, yielding a total of 32 RO participant-specific episode payments for Dual participants and a total of 16 RO participant-specific episode payments for Professional participants and Technical participants. In the CY 2022 OPPS/ASC proposed rule, we clarified that the total number of RO participant-specific episode payments for Dual participants and the total number of RO participant-specific episode payments for Professional participants and Technical participants will vary depending on the number of

included cancer types. For example, with the removal of liver cancer there are 15 included cancer types that yields a total of 30 RO participant-specific episode payment amounts for Dual participants and a total of 15 RO participant-specific episode payment amounts for Professional participants and Technical participants.

We did not solicit public comments on this clarification.

f. HOPD or Freestanding Radiation Therapy Center With Fewer Than Sixty Episodes During the Baseline Period

We codified at § 512.255(c)(7)(iv) a stop-loss limit of 20 percent for the RO participants that have fewer than 60 episodes from 2016 through 2018 and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of Specialty Care Models final rule (85 FR 61114). Under this stop-loss limit, CMS uses no-pay claims to determine what these RO participants would have been paid under FFS as compared to the payments they received under the RO Model and CMS pays these RO participants retrospectively for losses in excess of 20 percent of what they would have been paid under FFS. Payments under the stop-loss policy are determined at the time of reconciliation. We proposed to modify this stop-loss limit policy such that it applies to RO participants that have fewer than 60 episodes during the baseline period, as we proposed to define at § 512.205, and that were furnishing included RT services before the start of the model performance period in the CBSAs selected for participation and amend § 512.255(c)(7)(iv) accordingly.

We solicited public comments on our proposal in section XVIII.C.5.f. of the CY 2022 OPPS/ASC proposed rule (86 FR 42301).

The following is a summary of the public comments received on this proposal and our response:

Comment: Some commenters disagreed with the stop-loss policy. A few commenters stated that the stop-loss policy should apply to all RO participants, not just to RO participants that have fewer than 60 episodes during the proposed baseline period. Another commenter requested clarification as to why the stop-loss policy is limited in this way, because the number of episodes an RO participant furnishes is unrelated to case complexity, which the commenter believed is the reason for stop-loss policies in general. They cited the modeling of one entity's 2019 bone metastases episodes, which they believe demonstrates that under the Model, this entity would see a 66 percent rate reduction for that cancer type. Another commenter argued that limiting the stop-loss policy to entities with fewer than 60 episodes during the baseline period ignores the larger impact of financial loss that would be experienced by higher-volume entities serving large, vulnerable Medicare populations.

One commenter recommended that the stop-loss policy be applied to entities with gradually fewer episodes after PY1. A couple of commenters recommended a 20 percent stop-loss policy for rate variance per tumor site.

Response: We thank these commenters for their comments. We proposed to modify the stop-loss policy in only one respect, expanding one criterium of eligibility in that RO participants had to be furnishing included RT services ''before the start of the model performance period in the CBSAs selected for participation,'' instead of ''furnishing included RT services in the CBSAs selected for participation at the time of the effective date of the Specialty Care Models final rule'' as stated in that rule at 85 FR 61114. We received no comments on this specific proposal.

We refer to the Specialty Care Models final rule (85 FR 61177 through 61178) where we summarize and respond to comments on the stop-loss policy similar to those we received here. We would like to point out that those RO participants that have fewer than 60 episodes in the baseline period would not receive an historical experience adjustment. The heavy weight of the RO participants' historical experience in their participant-specific RO payment amount would prevent most if not all of RO participants from qualifying for the stop-loss policy if an historical experience adjustment were applied, particularly in the early PYs of the Model.

We are finalizing the policy as proposed such that those RO participants that had begun furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation are eligible for such a stop-loss limit and amend § 512.255(c)(7)(iv) accordingly.

g. Apply Adjustments for HOPD or Freestanding Radiation Therapy Center With a Merger, Acquisition, or Other New Business Relationship, With a CCN or TIN Change

We codified at § 512.210(a) those entities that must participate in the RO Model, and as more fully described at 85 FR 61195, an entity must participate in the RO Model if it has a new TIN or CCN that results from a merger, acquisition, or other new clinical or business relationship that occurs prior to October 3, 2025, begins to furnish RT services within a CBSA selected for participation, and meets the RO Model's eligibility requirements. We finalized a requirement for advance notification regarding a new merger, acquisition, or other new clinical or business relationships so that the appropriate adjustments would be made to the new or existing RO participant's participant-specific professional episode payment and participant-specific technical episode payment amounts. We finalized that RO participants must also provide a notification regarding a new clinical relationship that may or may not constitute a change in control, and if there were sufficient historical data from the entities merged, absorbed, or otherwise changed as a result of this new clinical or business relationship, then this data would be used to determine adjustments for the new or existing TIN or CCN. We also note that RO participants are required to report a change in control under § 512.180(c).

We proposed to add § 512.255(c)(14) to establish that we would calculate in accordance with § 512.255(c)(3) the RO participant's case mix adjustments based on all episodes and RO episodes, as applicable, attributed to the RO participant's legacy TIN(s) or legacy CCN(s) during the 3-year period that determines the case mix adjustment for each PY and all episodes and RO episodes, as applicable, attributed to the RO participant's current TIN or CCN during the 3-year period that determines the case mix adjustment for each PY. We also proposed that we would calculate the RO participant's historical experience adjustments in accordance with § 512.255(c)(4) based on all episodes attributed to the RO participant's legacy TIN(s) or legacy CCN(s) during the baseline period and all episodes attributed to the RO participant's current TIN or CCN during the baseline period. We proposed to eliminate the requirement that RO participants provide a notification regarding all new clinical or business relationships that may or may not constitute a change in control. We proposed to add § 512.210(e) requiring an RO participant to furnish to CMS written notice of a change in TIN or CCN in a form and manner specified by CMS at least 90 days before the effective date of any change in TIN or CCN that is used to bill Medicare.

We solicited public comments on our proposal in section XVIII.C.5.g. of the CY 2022 OPPS/ASC proposed rule (86 FR 42301).

The following is a summary of the public comments received on this proposal and our responses:

Comment: One commenter supported the policy to consider the legacy CCN(s) or TIN(s) for the purposes of risk adjustment, as this process is both straightforward and fair to the RO participant.

Response: We thank this commenter for their support.

We continue to believe that some new or altered clinical or business relationships may still pose risks of gaming in the RO Model, regardless of whether a change in control results. However, we believe that requiring RO participants to report changes to TINs or CCNs will capture the types of changes that pose these risks. This would also avoid any ambiguity as to what types of changes RO participants would need to report. After consideration of the comment we received, we are finalizing our policies as proposed with one technical change. We are adding subparagraphs to § 512.255(c)(14).

h. Discount Factor

We codified at both §§ 512.205 and 512.255(c)(8) that the discount factor for the PC would be 3.75 percent and the discount factor for the TC would be 4.75 percent. We proposed at 86 FR 42301 to lower the discount factor for the PC to 3.5 percent and the discount factor for the TC to 4.5 percent. Given our other proposed modifications to the RO Model, including removing brachytherapy and liver cancer, modifying the baseline period, and the current size of the RO Model (approximately 30 percent of eligible episodes), in the CY 2022 OPPS/ASC proposed rule at 86 FR 42301 we described that these modifications would enable us to lower these discounts without increasing the size of the RO Model due to a reduction in pricing variability and expecting to be able to detect a savings of 3.2 percent or greater at a significance level of 0.05 and with a power of 0.8. The definition of discount factor codified at § 512.205 also included the proposed percentages. To simplify the regulation text, we proposed to include the discount percentages at § 512.205 and remove the percentages from § 512.255(c)(8).

We solicited public comments on our proposal in section XVIII.C.5.h. of the CY 2022 OPPS/ASC proposed rule (86 FR 42301).

The following is a summary of the public comments received on this proposal and our response:

Comment: No commenters agreed with the proposed discounts, and many commenters proposed that discounts be set to 3 percent or less. Some commenters stated that they believe the RO pricing methodology fails to recognize that radiation oncology services rely heavily on the use of advanced technology and equipment that requires a significant financial investment. One of those commenters estimated that 85 percent of costs are equipment and technology related, and that beyond upfront capital investment in equipment, hospitals incur significant on-going costs related to software upgrades and equipment calibration. Furthermore, this commenter argued that the high-upfront investment costs and the proprietary nature of the equipment pose a barrier to switching vendors. Given this, the commenter stated that there are limited opportunities for RT providers and RT suppliers that are already adhering to evidence-based treatment guidelines to generate additional savings through internal cost reduction efforts.

One commenter noted that the proposed discounts, along with other aspects of the RO Model's pricing methodology, do not recognize the ongoing support of skilled staff necessary to operate a clinic. Many commenters specifically referenced the proposed discounts in combination with continued declines in MPFS payment rates as the source of their concern. They believe the combination will result in payment cuts that will put many RO participants in financial jeopardy.

One commenter stated the impact of the discount factor will be particularly acute for clinics in communities that serve patients who are more likely to be covered by Medicare or Medicaid programs, rather than privately funded employer-based health plans. According to the commenter, due to this payer mix, this group of physicians typically has more limited financial resources than their peers in other areas, making it difficult to invest in the resources necessary to participate in value-based payment programs. This commenter argued that as a result of this, the RO Model will exacerbate health disparities.

One commenter recommended that if CMS implements the RO Model during the COVID–19 PHE, that CMS gradually phase in the discount factor to allow time for RO participants to implement the systems necessary to succeed under the RO Model, retain the resources necessary to respond quickly to the ever-evolving PHE, and reinvest in a capital-intensive service line to ensure that access to care is maintained. One commenter stated its belief that in the event of a resurgence of the COVID–19 PHE or another nationwide emergency that leads to large disruptions in medical care, CMS should eliminate all downside risk for all participants as was done across models during the COVID–19 PHE in 2020.

Many commenters, recommending a discount factor of 3 percent or less, argued that this would be more in line with other payment models and ensure that radiation oncology providers have sufficient capital to remain operational and invest in the necessary resources (human and equipment) to increase efficiency and enhance beneficiary care. A few commenters recommended a discount of less than 3 percent to align with the discounts CMS applied to Oncology Care Model participants in a two-sided risk arrangement. A few commenters called attention to the discounts in both the Bundled Payment for Care Improvement-Advanced and Comprehensive Care for Joint Replacement (CJR) models. One commenter noted that the discounts in both models are no more than 3 percent, and that in CJR, hospitals that exhibit superior quality outcomes will have their discount factor reduced to as low as to 1.5 percent. Another commenter recommended CMS set lower discount rates for high performers, citing the CJR model as an example where CMS allows participants to earn back a percentage of the discount applied to the episodes based on quality performance. This commenter noted the recent finalized changes to the CJR model, which essentially eliminate the discount applied under the CJR model for the highest performing hospitals. One commenter recommended that CMS eliminate the discount factors altogether.

Response: We thank these commenters for expressing their concerns and for their suggestions. We designed the RO Model to test whether prospective episode payments in lieu of traditional FFS payments for RT services will reduce Medicare expenditures while preserving or enhancing quality. CJR finalized the elimination of the discount for high performers in PY6–8 so as to increase the accuracy of target prices compared to actual performance period spending. We would like to note that the RO Model's discount factors do not inform the accuracy of its episode pricing in the way that discounts do for CJR's pricing. We have made every effort to be responsive to stakeholder requests to lower the discount from what was finalized. In order to be able to detect an impact of the Model, we cannot further reduce the discounts beyond 3.5 percent and 4.5 percent for the PC and TC, respectively, without changing

other aspects of the Model, such as increasing the size of the Model. There has been no interest from stakeholders in increasing the number of CBSAs selected for participation in the Model.

As for the concern that the RO Model will exacerbate health disparities, we have no data or evidence to suggest that this will be the case. We believe that the RO Model presents a number of opportunities to minimize health disparities that currently exist. First, under the RO Model, RO participants will also have the opportunity to work collaboratively on performance improvement. The RO Model will offer shared communication platforms and educational webinars on specific topics of interest. These opportunities will enable RO participants to learn from their peer network and share best practices. CMS will also provide quarterly feedback reports to RO participants so they can better understand their individual patterns of care delivery, compare their data to other similar RO participants in the RO Model, and identify opportunities for quality improvement. In addition, RO participants can submit a DRA, requesting beneficiary line-level claims data, episode-level data, and participant-level data from CMS to help improve their patient care and care coordination.

At the beneficiary-level, we believe the RO Model has the potential to minimize health disparities in care. The potential for fewer treatments under the episode-based payment approach may lead to reduced side effects from treatment, reduced travel time required for treatment, less time spent in a doctor's office or waiting room, and more free time to engage in other activities that can help improve their overall quality of life. Furthermore, RO participants will be required to document an RO beneficiary's performance status to help inform the treatment plan and assess the effects of treatment on that individual and their quality of life. Every RO participant will be required to send a treatment summary to each RO beneficiary's referring physician to facilitate communication and coordination of care. Prior to the start of treatment, RO participants are also required to discuss with RO beneficiaries whether the goal of treatment is curative or palliative and the associated costs including cost-sharing responsibilities to facilitate shared decision-making. As we stated in the Specialty Care Models final rule (85 FR 61171), we plan to carefully monitor the RO Model for unintended consequences as finalized in sections III.C.14 (85 FR 61252) and III.C.16 (85 FR 61257). If our monitoring reveals that the Model reduces patient access to care, we would consider making changes to the Model via future rulemaking. Moreover, our evaluation will consider longer-term impacts on health outcomes associated with the Model.

We are finalizing as proposed the discount factor for the PC at 3.5 percent and the discount factor for the TC at 4.5 percent. We received no comments specifically on the proposed definition of discount factor, and therefore, we are finalizing as proposed to codify this definition at § 512.205, removing the percentages from § 512.255(c)(8). If the RO Model's scope were to increase at some point in the future via rulemaking, we could explore lowering the discount.

i. Withholds

We codified at § 512.255(c)(10) that we would apply a 2 percent quality withhold from each professional episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate. In the CY 2021 OPPS/ASC final rule (85 FR 85866), we delayed RO Model quality measures requirements to what would have been PY2 (January 1, 2022 through December 31, 2022) under the model performance period described in that final rule with comment and thus delayed the application of the quality withhold to that PY2. In the CY 2022 OPPS/ASC proposed rule, we proposed that RO participants submit quality measure data starting in PY1 (when the model performance period begins) as described in section XVIII.C.6. of the CY 2022 OPPS/ASC proposed rule, and that beginning in PY1, a 2 percent quality withhold for the PC would be applied to the applicable trended national base rates after the case mix and historical experience adjustments.

We solicited public comments on our proposal in section XVIII.C.5.i. of the CY 2022 OPPS/ASC proposed rule (86 FR 42301).

The following is a summary of the public comments received on this proposal and our response:

Comment: Some commenters disagreed with this proposal. A few commenters expressed concern, because they believe RO participants will not be able to earn back the full amount withheld, no matter how good the performance. One commenter recommended that the 2 percent quality withhold should not occur until PY2, as was originally proposed. Another commenter recommended that CMS allow RO participants the opportunity to earn back above their quality withhold based on quality performance just as CMS allows participants in the Direct Contracting model to qualify for a bonus above the participant's quality withhold from a High Performers Pool.

Response: We thank these commenters for expressing their concerns and for their suggestions. We believe that the upfront quality withhold will provide the incentive for RO participants to provide high-quality care. Further, we believe that the predetermined withholds help support the Model goal of providing RO participants with prospective, predictable payments. The quality withhold allows the Model to link quality to payment, which is a key requirement of QPP. Please note that Professional participants and Dual participants could earn up to the full amount of the quality withhold (2 percent of the professional episode payment amounts) for a given PY based on their performance on the AQS. Since we are collecting quality measures in PY1, it is necessary to have a quality withhold in PY1. Please note that we did not propose to change the amount of the quality withhold.

After consideration of the public comments, we are finalizing as proposed that RO participants submit quality measure data starting in PY1 (when the model performance period begins) as described in section XVIII.C.6. of the CY 2022 OPPS/ASC proposed rule, and that beginning in PY1, a 2 percent quality withhold for the PC will be applied to the applicable trended national base rates after the case mix and historical experience adjustments. We are codifying this policy at § 512.255(c)(10).

j. Adjustment for Geography

We described in the Specialty Care Models final rule (85 FR 61198) that the geographic adjustment whereby the RO Model-specific relative value unit (RVU) values would be derived from the national base rates which are based on 2016 to 2018 episodes that had the majority of radiation treatment services furnished at an HOPD and that were attributed to an HOPD. We finalized that we would use only 2018 episodes to calculate the implied RVU shares. We proposed in the CY 2022 OPPS/ASC proposed rule to modify this provision to align with the proposed model performance period so that the final year of the baseline period would be used to calculate the implied RVU shares. For example, for a baseline period of 2017–2019, 2019 would be used to calculate the implied RVU shares.

We solicited public comments on our proposal to use the final year of the baseline period to calculate the implied RVU shares in the CY 2022 OPPS/ASC proposed rule (86 FR 42302).

We received no comments and therefore, we are finalizing our proposal without modification to use the final year of the baseline period to calculate the implied RVU shares.

k. Example of Participant-Specific Professional Episode Payment and Participant-Specific Technical Episode Payment for an Episode Involving Lung Cancer in PY1

In section XVIII.C.5.k of the CY 2022 OPPS/ASC proposed rule (86 FR 42304), we noted that we are analyzing whether the COVID–19 PHE resulted in a decrease in Medicare FFS claims submissions for RT services during 2020 relative to historical levels. For this reason, under the extreme and uncontrollable policy proposed in section XVIII.C.10. of the CY 2022 OPPS/ASC proposed rule, pending 12-months of claims run-out for RT services furnished in 2020, we described that we would consider the removal of 2020 data from the calculation of any applicable baseline period or trend factor. We also noted that we are not considering the exclusion of 2020 from the case mix adjustment at this time, because the case mix episodes are weighted equally (unlike the baseline period, where more recent episodes are given more weight than earlier episodes), and the case mix adjustment does not rely on the volume of RT services furnished.

We solicited public comments on our EUC policy as it concerns pricing methodology and the use of certain episode data (86 FR 42311 through 42312). We have summarized and responded to comments in that section.

6. Quality-Form, Manner, and Timing for Quality Reporting

In the Specialty Care Models final rule (85 FR 61220 through 61223), we finalized that the RO Model quality measure reporting will be based on a CY. We also stated in that final rule at 85 FR 61222, that in selecting measures for the RO Model, we sought to include a set of meaningful, parsimonious measures, reflective of the CMS Meaningful Measures framework that balances the need for data about participant performance without creating undue burden on participants. One set of measures used by all RO participants will provide insight for CMS and the radiation oncology field as a whole into how care quality compares across multiple markets. Selective or limited reporting of measures would hinder the ability of CMS to measure or analyze the impact of the Model on quality. In the CY 2021 OPPS/ASC final rule, we delayed RO Model quality measures requirements to PY2 (January 1, 2022 through December 31, 2022). We proposed in in section XVIII.C.6. of the CY 2022 OPPS/ASC proposed rule that Professional participants and Dual participants submit quality measure data starting in PY1 during the proposed model performance period (86 FR 42306 through 42307). Under this proposal, if the proposed model performance period starts mid-year, the CY collection period would remain the same as if the model performance period began on January 1. For example, if the model performance period starts in July, RO participants would collect quality measure data for that CY starting in January, allowing RO participants to use their MIPS data submission to meet the RO Model requirements.

We solicited public comments on our proposal in section XVIII.C.6 of the CY 2022 OPPS/ASC proposed rule (86 FR 42306 through 42307).

The following is a summary of the public comments received on this proposal and our response:

Comment: We received many comments from RO participants stating that they will not be ready to start gathering quality measure data on January 1, 2022, in order to report for PY1. Commenters stated that the requirements were extensive and additional time would be required to develop new processes and procedures.

Response: We thank commenters for their comments. The RO Model was finalized to start January 1, 2021, in the Specialty Care Model final rule (85 FR 61135 through 61137) and RO participants were notified at that time of their inclusion in the RO Model when that final rule was published in September 2020. RO participants have had over a year to prepare for their participation in the RO Model. When the CY 2022 OPPS/ASC proposed rule was published, CMS released the Quality Measure and Clinical Data Elements Guide on the RO Model website, along with the associated CDE templates for each of the five cancer types. We have provided education and outreach support to encourage the efficient collection and submission of this data, including a webinar related to Model requirements in September 2021 to help RO participants prepare for the various requirements. We have additional webinars planned specifically on the QPP, and quality measures and CDEs. Therefore, we believe that RO participants have had adequate time to prepare.

We direct readers to section XVII.C.10 of this final rule with comment period, which discusses our proposal and decision to finalize an EUC policy that would allow CMS flexibility in responding to national, regional, or local circumstances that adversely impact RO participants' ability to deliver care in accordance with the RO Model's requirements, including the COVID–19 PHE. The EUC policy will give CMS the ability to delay some of these quality measure and CDE reporting requirements, as needed.

Comment: Many commenters recommended changes to the quality measure process. Many commenters asked for a voluntary phase-in period to collect quality measure data, which they believe would allow RO participants to become operational within the RO Model and provide better data. We received many comments asking CMS to delay the implementation of data collection for 2 years, while one commenter requested an 18-month delay.

Response: We proposed that RO participants' first submission for the set of quality measures for PY1 (beginning on January 1, 2022) in section XVIII.C.8.b. of the CY 2022 OPPS/ASC proposed rule, would occur in March 2023, based on the timeline finalized in the Specialty Care Models final rule at 85 FR 61211 (footnote 44). We believe beginning the model performance period on January 1, 2022 will allow RO participants to review and to develop best practices to facilitate their data collection and to work with EHR vendors to seek additional EHR support as necessary. We have also done outreach to vendors since the Specialty Care Models final rule published in 2020 to help prepare them for the start of the RO Model.

Comment: A couple of commenters urged CMS to provide additional details on quality measure and CDE collection and submission processes to give RO participants additional time to prepare their systems and comply with these requirements. One commented asked for additional tools and supportive resources up front to aid in implementation. The same commenter asked for an expansion of collection types and reporting mechanisms for the quality measures in order to align with quality reporting programs in other models.

Response: When the CY 2022 OPPS/ASC proposed rule was published, CMS released the Quality Measure and Clinical Data Elements Guide on the RO Model website, along with the

associated CDE templates for each of the five cancer types [569]. This guide may be updated in the future to include additional details on implementation. We have provided education and outreach support to encourage the efficient collection and submission of this data, including a webinar related to Model requirements in September 2021 to help RO participants prepare for the various requirements, and we have additional webinars planned specifically on the QPP program and quality measures and CDEs.

Comment: A few commenters opposed the implementation of quality measures in the RO Model, stating that the measures would not yield information reflective of quality in a radiation oncology practice and would do little to encourage actual improvement in the quality of patient care.

Response: We disagree with commenters' assertions regarding the impact of quality measurement in the RO Model. As we discussed in the Specialty Care Models final rule (85 FR 61214), we believe that the measures we are adopting are appropriate for inclusion in the RO Model. We selected all measures based on clinical appropriateness for RT services spanning a 90-day episode period. We believe that radiation oncologists have an important role to play in ensuring that their patients have a plan to address pain, that they communicate treatment with other providers and suppliers to ensure the RO beneficiaries are receiving coordinated care, and that they have been screened for depression and have an advance care plan. By encouraging radiation oncologists to provide guidance and care coordination as well as engage with patients throughout their treatments, we believe these measures will improve both patients' outcomes and their experience of care. We believe both depression screening and advance care planning help RO beneficiaries ensure they are engaged and pursuing the best course of treatment for them. We believe that including appropriate quality measures in the RO Model—as in other Innovation Center Alternative Payment Models (APMs)—is critical to ensuring that quality of care is preserved or enhanced within an episode payment model testing whether CMS expenditures are reduced. Furthermore, if we did not finalize quality measures for the RO Model, it would not satisfy the criteria to be an Advanced APM or a MIPS APM.

Comment: One commenter asked that CMS retain two of the finalized quality measures but consider revising the full list to focus on the work of radiation oncologists with Medicare patients. The same commenter asked that we revise the specifications for all quality measures in the RO Model to only include Medicare patients in the denominator.

Response: As stated in the Specialty Care Models final rule (85 FR 61220) we believe collecting data for all patients who meet the denominator specifications for each measure from a Professional participant or Dual participant, and not just Medicare beneficiaries, is appropriate because it is consistent with the applicable measure specifications, and any segmentation to solely the Medicare populations would be inconsistent with the measure and add substantial reporting burden to RO participants. We continue to believe that reporting on all-payer data is important to improve and drive the quality of care furnished to all patients, including Medicare beneficiaries.

Comment: Many commenters expressed concern that EHR vendors will use the new requirements to generate additional fees for their products, thereby placing RO participants, especially those that are small and rural, at greater financial risk.

Response: We understand the commenters' concern about the cost of these requirements, but we note that three of the four proposed quality measures are already included in the MIPS program, so we expect that some of these measures may already be familiar to EHR vendors. We believe that the quality measures and CDEs can be collected manually if desired, which would not require payment of additional fees to EHR vendors.

After consideration of the comments received, we are finalizing as proposed that Professional participants and Dual participants submit quality measure data starting in PY1 of the model performance period.

We also proposed that for PY1, Professional participants and Dual participants would be required to submit data for three pay-for-performance measures: (1) Plan of Care for Pain; (2) Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan. Professional participants and Dual participants would be required to submit data on a fourth measure, Treatment Summary Communication—Radiation Oncology, as a pay-for-reporting measure. All quality measure data will be reported using the RO Model secure data portal in the manner consistent with that submission portal and the measures' specifications. We intend to use data submitted by Professional participants and Dual participants for the Treatment Summary Communication—Radiation Oncology measure in PY 1 and PY2 to propose a benchmark to re-specify it as a pay-for-performance measure, for PY3.

We proposed that we may update the specifications for the Treatment Summary Communication—Radiation Oncology measure, should new specifications from the measure's steward meet the RO Model's needs. Any non-substantive updates to the specifications for this measure would be communicated in a form and manner specified by CMS. Any substantive changes to measure specifications would be addressed through notice and comment rulemaking.

We solicited public comments on our proposal in section XVIII.C.6. of the CY 2022 OPPS/ASC proposed rule (86 FR 42307).

The following is a summary of the public comments received on this proposal and our response:

Comment: One commenter agreed with the proposal.

Response: We thank the commenter.

Comment: We received some comments disagreeing with the proposal because the Treatment Summary Communication—Radiation Oncology measure is not NQF-endorsed, is not an outcome measure, is burdensome, and is not used in other CMS programs.

Response: We believe that updated specifications for the Treatment Summary Communication—Radiation Oncology measure may allow for easier implementation of the quality measure and reduced burden. While NQF endorsement and status as an outcome measure are important criteria to consider in the selection of quality measures, we continue to believe that the information captured by this measure is relevant to the RO Model and critical to patients' care continuity and coordination.

After consideration of the comments received, we are finalizing as proposed that we may update the specifications for the Treatment Summary Communication—Radiation Oncology measure, should new specifications from the measure's steward meet the RO Model's needs. Any non-substantive updates to the specifications for this measure will be communicated in a form and manner specified by CMS. Any substantive changes to measure specifications will be addressed through notice and comment rulemaking.

[569] These documents are currently located at *https://innovation.cms.gov/innovation-models/radiation-oncology-model*. If newer versions are posted, these documents will be moved to *https://innovation.cms.gov/innovation-models/radiation-oncology-archived-materials*.

We finalized that we would have a CMS-approved contractor administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Cancer Care Survey for Radiation Therapy, beginning in April 2021 (85 FR 61220). In the CY 2021 OPPS/ASC final rule, we revised this policy so that a CMS-approved contractor would administer the CAHPS® Cancer Care Survey for Radiation Therapy beginning in October 2021. Given the change in model performance period due to the delay under section 133 of the CAA 2021, we proposed in section XVIII.C.6 of the CY 2022 OPPS/ASC proposed rule (86 FR 42307) that we would amend existing policy such that the CMS-approved contractor will begin administering the CAHPS® Cancer Care Survey for Radiation Therapy on behalf of the RO participants and CMS as soon as there are completed RO episodes, no earlier than the fourth month of the model performance period.

We solicited public comments on our proposal in section XVIII.C.6 of the CY 2022 OPPS/ASC proposed rule (86 FR 42307).

The following is a summary of the public comments received on this proposal and our response:

Comment: One commenter supported our proposal.

Response: We thank the commenter.

Comment: Some commenters requested additional clarification on future pay-for-performance use of the CAHPS® Cancer Care Survey for Radiation Therapy, requested clarification of sampling of the CAHPS® Cancer Care Survey for Radiation Therapy, suggested use of a web-based data collection mode, requested clarification on overlap with non-RO Model uses of CAHPS® surveys, or requested modifications to account for low patient survey response rates.

Response: We appreciate these comments; however, they are not related to our proposal. Please refer to our policies related to the CAHPS® Cancer Care Survey for Radiation Therapy in the Specialty Care Models final rule (85 61219–61220). We may consider other comments on the CAHPS® Cancer Care Survey for Radiation Therapy in future notice and comment rulemaking.

After consideration of the comments received, we are finalizing without modification our proposal that the CMS-approved contractor will begin administering the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Cancer Care Survey for Radiation Therapy as soon as there are completed RO episodes, no earlier than the fourth month of the model performance period.

In the Specialty Care Models final rule at 85 FR 61223 we discussed that in selecting CDEs for the RO Model, we sought to balance the need for data about participant performance without creating undue burden on participants. In that same final rule (85 FR 61223 through 61226), we finalized under the RO Model's clinical data collection policy that Professional participants and Dual participants must collect certain clinical information not available in claims or quality measures, with data collection starting in PY1. In the CY 2021 OPPS/ASC final rule (85 FR 86262), we revised this policy so that the collection period for CDEs would begin on January 1, 2022. We proposed in section XVIII.C.6 of the CY 2022 OPPS/ASC proposed rule (86 FR 42307) that Professional participants and Dual participants submit CDEs starting in PY1.

We solicited public comments on our proposal in section XVIII.C.6 of the CY 2022 OPPS/ASC proposed rule (86 FR 42307).

The following is a summary of the public comments received on this proposal and our response:

Comment: We received a few comments asking for changes to the reporting timeline for the CDEs. A few commenters asked that the reporting period for the CDEs align with the quality measures so there is one reporting period every year in March. Many commenters expressed concern that the CDEs would need to be manually reported, which would take time and resources. One commenter asked that the CDE reporting requirement under the RO Model be delayed for two years to allow time for RO participants to develop work flows and work with EHR vendors. Many commenters asked that we select CDEs that can be extracted from EHRs and linear accelerators.

Response: While we appreciate that commenters may prefer streamlined reporting periods, we believe that it is important to capture the CDEs twice per year to allow for appropriate monitoring of the RO Model and support early work on the development of outcomes-based quality measures. In contrast, we do not believe that twice per year quality measure data reporting is necessary as it is not used in the development of new outcomes-based quality measures. CMS has shared the CDEs and templates with vendors to facilitate the work needed to extract the CDEs from their EHR systems.

Comment: We received a few comments asking that we reduce the CDE reporting threshold lower than 95 percent.

Response: We believe that the 95 percent threshold is important to ensure the quality and usability of the CDEs received by CMS. By maintaining the 95 percent threshold, CMS will maximize its ability to support monitoring and evaluation of the Model and begin developing new outcome-based quality measures. A reduction in this threshold may jeopardize the ability to draw conclusions from data received from RO participants, thus defeating the purpose of the CDEs.

Comment: We received a comment stating that CDEs should not be captured unless they will be used to risk adjust quality performance or to set payment rates.

Response: As we described in the Specialty Care Models final rule at 85 FR 61223, these data may be used to inform future refinements to the RO Model.

After consideration of comments received, we are finalizing as proposed that Professional participants and Dual participants submit CDE data starting in PY1 of the model performance period.

7. RO Model as an Advanced Alternative Payment Model (Advanced APM) and a Merit Based Incentive Payment System APM (MIPS APM)

At the time of the publication of the Specialty Care Models final rule, the model performance period began on January 1, 2021 and ended December 31, 2025 (42 CFR 512.205). We finalized in the Specialty Care Models final rule the policy that we expected the RO Model to meet the criteria to be an Advanced APM and a MIPS APM under the Quality Payment Program beginning in PY1 of the RO Model.

In the CY 2021 OPPS/ASC final rule (85 FR 86262), we finalized our proposal to amend this policy to reflect that we anticipated that the RO Model will meet the criteria to be both an Advanced APM and a MIPS APM under the Quality Payment Program starting in PY2 which would begin on January 1, 2022. Despite the delay required by the CAA, 2021, we expect the RO Model to meet the criteria to be an Advanced APM and a MIPS APM beginning in PY1, beginning January 1, 2022. Final CMS determinations of Advanced APM status and a list of MIPS APMs for the 2022 performance period will be announced via the Quality Payment Program website at *https://qpp.cms.gov/*. We anticipate that the RO Model will meet the Advanced APM criteria, reflected in our regulation at § 414.1415 in PY1 and all subsequent PYs.

As stated in the CY 2022 OPPS/ASC proposed rule, the first criterion to be an Advanced APM is set forth at

§ 414.1415(a), CEHRT use. For the RO Model, this criterion is satisfied by the requirements of § 512.220(b), that RO participants must use CEHRT; that the RO participant must annually certify its use of CEHRT during the model performance period; and that the RO participant will be required to certify its use of CEHRT within 30 days of the start of each PY (86 FR 42307).

As stated in the CY 2022 OPPS/ASC proposed rule, the second criterion to be an Advanced APM is at § 414.1415(b), Payment based on quality measures. This criterion is satisfied because payment under the RO Model is based on MIPS-comparable quality measures, as specified in regulation at § 414.1415(b). Specifically, the RO participant will have their payment amount adjusted by the 2 percent quality withhold with the chance of earning back some or all of that amount based on their AQS, as codified at § 512.255(c)(10). For further discussion of these requirements, please see the Specialty Care Models final rule at 85 FR 61211 through 61231.

As stated in the CY 2022 OPPS/ASC proposed rule, the third criterion to be an Advanced APM is set forth at § 414.1415(c), Financial Risk. This criterion is satisfied by the application of the discount factor to RO Model payments, codified at § 512.255(c)(8); the application of the quality withhold to the RO Model payments, codified at § 512.255(c)(10); and the fact that RO participants are responsible for 100 percent of all expenditures in excess of the expected amount of expenditures beyond those covered by the participant-specific professional episode payment or the participant-specific technical episode payment as codified at § 512.265, with the exception of those RO participants that qualify for the stop-loss policy as codified at § 512.285(f). The finalized changes to the stop-loss policy described in section XVII.C.5.f. and the discount amounts described in section XVII.C.5.h. of this final rule with comment period do not affect the satisfaction of the Financial Risk criterion.

As finalized in the CY 2021 OPPS/ASC final rule at 85 FR 61237, and reiterated in the CY 2022 OPPS/ASC proposed rule, for the subset of RO participants that are limited to the total amount of losses they may incur because they are eligible for the stop-loss policy, that limit is set to 20 percent of expected expenditures for which the RO participants are responsible for under the RO Model. Therefore, even when the RO Model stop-loss policy is applicable, the RO Model still meets the Financial Risk criterion to be an Advanced APM, which is 3 percent of the expected expenditures for which an APM Entity is responsible under the APM, at § 414.1415(c)(3)(i)(B).

As stated in the CY 2022 OPPS/ASC proposed rule, the MIPS APM criteria at § 414.1367(b) specify that APM entities in a MIPS APM must participate in the APM under an agreement with CMS or through a law or regulation, and the APM must base payment on quality measures and cost/utilization. Professional participants and Dual participants are required to report quality measures, as codified at § 512.275(c), and the RO Model meets the quality measure and cost/utilization requirement through the application of the quality withhold, codified at § 512.255(c)(10), and the use of the Aggregate Quality Score (AQS) and its application to the quality withhold, as finalized at 85 FR 61226 through 61231. Pursuant to §§ 414.1317 and 414.1367, MIPS eligible clinicians who are identified on a participation list of an APM Entity participating in a MIPS APM during the performance period have unique reporting options under MIPS.

We clarified in the CY 2022 OPPS/ASC proposed rule (86 FR 42308) that Professional participants and Dual participants who meet the RO Model requirements codified at § 512.220, including use of CEHRT, and who are eligible clinicians on a Participation List as those terms are defined at § 414.1305, would fall into a category called ''Track One'' of the RO Model. We noted that RO Model participants in Track One would be considered to be participating in the Advanced APM track of the RO Model, and we would make Qualifying APM Participant (QP) determinations for the eligible clinicians on the RO Model Participation List for Track One as provided in § 414.1425. In the CY 2022 OPPS/ASC proposed rule, we stated that we anticipated that Track One of the RO Model would also meet the criteria to be a MIPS APM under the definition at § 414.1305 starting January 1, 2022 (86 FR 42307). If eligible clinicians who are Track One RO Participants do not meet the thresholds to become QPs, they can report to MIPS using reporting options applicable to MIPS APM participants as specified at § 414.1367.

We also proposed in the CY 2022 OPPS/ASC proposed rule that, at the start of a PY, if Professional participants or Dual participants failed to meet any of the RO Model requirements codified at § 512.220, which includes use of CEHRT, they would be moved into a separate category called ''Track Two'' of the RO Model for that PY (86 FR 42308). We proposed to define ''Track Two'' to mean an APM for Dual participants and Professional participants who do not meet the RO Model requirements set forth at § 512.220 and for all Technical participants. RO participants that fall into Track Two would not be participating in an Advanced APM or MIPS APM for the RO Model. As such, we would not make QP determinations for the eligible clinicians on the RO Model Participation List for Track Two. We proposed to codify definitions for ''Track One'' and ''Track Two'' at § 512.205. If an RO participant meets the CEHRT use requirements pursuant to § 414.1415(a)(1)(i) by the last QP determination snapshot date specified at § 414.1325, they would be moved to Track One of the RO Model and would be considered at that point to be participating in an Advanced APM, provided the RO participant meets all other RO Model requirements set forth at § 512.220.

In the CY 2022 OPPS/ASC proposed rule, we stated that we recognized that any failure, however minor, to comply with the RO Model requirements set forth at § 512.220(a)(2) would have an impact on whether an RO Model participant is in Track One versus Track Two. Section 512.220(a)(2) contains a number of requirements, including requirements to discuss goals of care and RO Model cost-sharing responsibilities with each RO beneficiary; adhere to nationally recognized, evidence-based clinical treatment guidelines when appropriate; assess each RO beneficiary's tumor, note, and metastasis cancer stage; and send a treatment summary to each RO beneficiary's referring physician within 3 months of the end of the treatment. Under our proposal, any failure to comply with the requirements of § 512.220(a)(2) would have resulted in Track Two status for the RO participant and would be subject to remedial action under § 512.160. However, we recognized that an RO participant's noncompliance with the terms of § 512.220(a)(2) might not be discovered until after CMS has treated the RO participant as if they were in Track One, including potentially making QP determinations for an RO participant's eligible clinicians and making APM Incentive Payments (or, in years beginning with CY 2026, applying a differentially higher update under the Physician Fee Schedule) (86 FR 42308). In that event, the payments we would make based on the QP status of the RO participant's eligible clinicians pursuant to its Track One status would constitute overpayments. We are concerned that,

in the case of minor noncompliance with the requirements of § 512.220(a)(2), such overpayment liability may be too harsh. We considered removing the requirement that RO Model participants must meet all of the requirements codified in § 512.220(a)(2) to remain in Track One, but feel that these requirements are important to quality improvement in radiation oncology. We noted in the CY 2022 OPPS/ASC proposed rule that we were considering whether the final rule should modify some of the requirements in § 512.220(a)(2). For example, instead of requiring certain actions for ''each RO beneficiary,'' we were considering whether to require those actions for a majority of RO beneficiaries or substantially all RO beneficiaries. In addition, we noted that we were considering whether to modify certain requirements to permit payment of some or all of the payments made based on the QP status the RO participant's eligible clinicians pursuant to its Track One participation, depending on the severity of noncompliance and other factors (86 FR 42308).

We solicited public comments on these proposals, including whether the RO Model can meaningfully improve the quality of care if any of the requirements specified in § 512.220(a)(2) are modified, which requirements would be appropriate for modification, the impact of recoupment, and if there are more effective ways to encourage quality improvement and Track One participation in section XVIII.C.7 of the CY 2022 OPPS/ASC proposed rule (86 FR 42308).

The following is a summary of the public comments received on this proposal and our response:

Comment: A few commenters agreed with our proposal as a whole. Many commenters asked that CMS remove the Track One and Track Two policy as it makes it more difficult for RO participants to achieve QP status or was otherwise unfair to some RO participants.

Response: We appreciate the commenters' concerns. We would like to note that the definitions of Track One and Track Two were only added as a clarification for RO participants. Removing Track One and Track Two would not, in fact, make it easier for an RO participant to meet QP status as it might disqualify the entire RO Model from being an Advanced APM and a MIPS APM.

Further, in order to better align the RO Model with the QPP, and in response to these comments, we are creating three categories for RO participants, ''Track One'', ''Track Two'', and ''Track Three'' codified at § 512.205. Structurally, Track One as proposed will now be divided into two tracks and Track Two as proposed will become Track Three. Track One will be for RO participants who comply with all RO requirements, including CEHRT, and we anticipate that Track One will be both an Advanced APM and MIPS APM. Track Two will be for those RO participants who comply with all RO requirements except for CEHRT, and we anticipate that Track Two will be a MIPS APM, but would not meet the CEHRT use criterion to be an Advanced APM. Track Three will be for all other RO participants, and we anticipate that Track Three will not be an Advanced APM or MIPS APM. We believe that identifying these three tracks is responsive to some of the concerns raised by these commenters. This change would create an incentive for RO participants that are not able to implement CEHRT to be compliant with other aspects of the RO Model in order to participate in a MIPS APM. This also avoids misalignment of RO Model tracks with the MIPS APM criteria, which do not require CEHRT.

After considering public comments, we are finalizing with modification the definitions of Track One, and Track Two, and adding a definition for Track Three. We are finalizing the definition of Track One to mean a track for Professional participants and Dual participants that meet all RO Model requirements set forth at § 512.220, including use of CEHRT. Consistent with this definition, we anticipate that RO Model participants in Track One will be considered to be participating in an Advanced APM and MIPS APM under the RO Model, and we will make Qualifying APM Participant (QP) determinations for the eligible clinicians on the RO Model Participation List for Track One as provided in § 414.1425. We anticipated that Track One of the RO Model would also meet the criteria to be a MIPS APM under the definition at § 414.1305 starting January 1, 2022. If eligible clinicians who are Track One RO Participants do not meet the thresholds to become QPs, can report to MIPS using reporting options applicable to MIPS APM participants as specified at § 414.1367.

We are finalizing the definition of Track Two to mean a track for Professional participants and Dual participants that meet all RO Model requirements set forth at § 512.220, except for use of CEHRT. That is, a Dual participant or Professional participant who does not use CEHRT but meets all other RO Model requirements set forth at § 512.220 would be in Track Two. We anticipate that RO participants in Track Two will be considered to be participating in a MIPS APM under the RO Model.

We are finalizing the definition of Track Three to mean a track for Professional participants and Dual participants who do not meet one or more of the RO Model requirements set forth at § 512.220(a); and for all Technical participants. For example, a Professional participant or Dual participant that does not adhere to nationally recognized, evidence-based clinical treatment guidelines when appropriate would be in Track Three. We anticipate that RO participants that fall into Track Three will be considered to be participating in an APM, but not in an Advanced APM or MIPS APM, under the RO Model. As such, we will not make QP determinations for the eligible clinicians on the RO Model Participation List for Tracks Two and Three. And eligible clinicians on the RO Model Participation List for Track Three will not have the unique MIPS reporting options available to participants in a MIPS APM (though they will receive MIPS Improvement Activity scoring credit for participation in an APM). We are codifying these definitions at § 512.205.

We would also like to note that we are not modifying any requirements to permit payment of some or all of the payments made based on the QP status of the RO participant's eligible clinicians pursuant to its Track One participation, depending on the severity of noncompliance and other factors.

a. Technical Participants and the Quality Payment Program

In the CY 2022 OPPS/ASC proposed rule, we proposed that Technical participants that are freestanding radiation therapy centers (as identified by a TIN) that only provide the technical component (TC), are not required to report quality measures under the RO Model, and fall into Track Two of the RO Model. We proposed that Technical participants would not be considered to be participating in Advanced APMs or MIPS APMs under the RO Model. However, Technical participants that are freestanding radiation therapy centers would be able to attest to their participation in an APM for purposes of MIPS, and may be eligible to receive Improvement Activity credit as specified at § 414.1317(b)(3).

In the CY 2022 OPPS/ASC proposed rule, we also proposed that if the Technical participants that are freestanding radiation therapy centers (as identified by a TIN) begin providing the PC at any point during the model

performance period, then they must notify CMS within 30 days, in a form and manner specified by CMS. We proposed that they would also be required under the RO Model to report quality measures by the next reporting period, which would be March following a PY for quality measures and July of a PY or January following a PY for the CDEs, as finalized at 85 FR 61211 through 61231. If they meet the requirements to be a Track One RO participant at one of the QP determination dates specified in § 414.1425(b), they would be considered to be participating in an Advanced APM and a MIPS APM. Once a Technical participant that is a freestanding radiation therapy center begins providing the professional component, the freestanding radiation therapy center becomes a Dual participant as defined in § 512.205. We noted that we would monitor these RO participants for compliance with the requirement to report quality measures if they begin providing the professional component. We proposed to codify this policy at § 512.275(d).

We solicited public comments on our proposal in section XVIII.C.7.a. of the CY 2022 OPPS/ASC proposed rule (86 FR 42308 through 42309). The following is a summary of the public comments received on this proposal and our response:

Comment: CMS received many comments asking that Technical participants be eligible for QP determination. Some commenters noted that the APM Incentive Payment is not only an incentive to participate in the Model, but these commenters believe that it is also designed to support practice transformation essential for meaningful APM participation. According to the commenters, the RO Model participation requirements establish new, unreimbursed practice expenses that would normally be paid from technical fee revenue. Unless the APM Incentive Payment is applied to both the professional and technical charges, the commenter stated that those RO participants will be at a distinct disadvantage and unable to achieve true practice transformation.

Response: We appreciate the commenters' concerns regarding Technical participant eligibility for QP determination. We understand that the APM Incentive Payment can support practice transformation, but we do not agree with the commenter that purpose of the APM Incentive Payment is to support practice transformation for meaningful APM participation. Please refer to § 414.1450 for more information on the APM Incentive Payment. We disagree with the commenters that Technical participants should be eligible for QP determinations under the RO Model. We continue to believe that eligibility for QP determination should be limited to Professional participants and Dual participants. This model is intended to be site neutral, meaning that Technical participants that are freestanding radiation therapy centers paid under the PFS and Technical participants that are HOPDs paid under the OPPS should be treated equally. The majority of Technical participants are HOPDs and are not subject to QPP and there are only a few freestanding radiation therapy centers that furnish only the TC. We would also note that Technical participants are not required to report quality measures or clinical data, or to have CEHRT, under the RO Model.

After considering public comments, we are finalizing as proposed our proposals related to Technical participants that are freestanding radiation therapy centers. We would like to add one non-substantive change to the text of the CY 2022 OPPS/ASC proposed rule. We proposed that Technical participants would not be considered to be participating in Advanced APMs or MIPS APMs under the RO Model. We would like to clarify this text to state that we proposed that Technical participants will not be participating in Track One or Track Two of the RO Model, and are therefore would not be participants in an Advanced or MIPS APM under the RO Model.

We have also removed the regulation at § 512.217(c)(3)(iii) that Technical participants that are freestanding radiation therapy centers would be able to attest to their participation in an APM for purposes of MIPS, and may be eligible to receive Improvement Activity credit as specified at § 414.1317(b)(3), as this language was unnecessary. All participants in APMs are evaluated for Improvement Activity credits under MIPS (§ 414.1355).

We are codifying these policies related to Technical participants that are freestanding radiation therapy centers at § 512.275(d). We are also revising for clarification the notice requirement language at § 512.275(d)(1) to remove the duplicative use of the term ''certify.''

b. Individual Practitioner List

In the Specialty Care Models final rule, we finalized our proposal to codify the requirements concerning the review and certification of the individual practitioner list at § 512.217. In the CY 2021 OPPS/ASC final rule (85 FR 86262), we amended this regulation so that the individual practitioner list was not to be used for QP determinations or for determining participants in a MIPS APM for purposes of MIPS reporting and scoring rules in PY1, and the individual practitioner list was to only be used for the QPP in PY1 to assign an automatic 50 percent score for the Improvement Activity performance category in MIPS for RO participants. This amendment stated that starting in PY2 (January 1, 2022), the individual practitioner list was to be used to identify the relevant eligible clinicians for the purpose of making QP determinations and for certain aspects of MIPS under the Quality Payment Program. The CAA, 2021 prohibits implementation of the RO Model prior to January 1, 2022. We clarified in section XVIII.C.7.b of the CY 2022 OPP/ASC proposed rule that all requirements concerning the review and certification of the individual practitioner list finalized and codified at § 512.217 will remain in effect starting on the first day of the model performance period (86 FR 42309).

In the Specialty Care Models final rule, we codified at § 512.217(a) that upon the start of each PY, CMS creates and provides to each Dual participant and Professional participant an individual practitioner list which identifies by NPI each individual practitioner associated with the RO participant.

We proposed in section XVIII.C.7.b of the CY 2022 ASC/OPPS proposed rule to modify this policy to include that Technical participants that are freestanding radiation therapy centers would also be provided an individual practitioner list (86 FR 42309). We also proposed to add to the regulation at § 512.217(b) that in the case of a Dual participant, Professional participant, or Technical participant that is a freestanding radiation therapy center, which begins participation in the RO Model after the start of a given PY, but at least 30 days prior to the last QP determination snapshot date specified at § 414.1325, of that PY, CMS would create and provide the new Dual participant, Professional participant, or Technical participant that is a freestanding radiation therapy center with an individual practitioner list. Any new Dual participant, Professional participant, or Technical participant that is a freestanding radiation therapy center that begins participation in the RO Model after the start of the PY must review and certify their individual practitioner list by the last QP determination snapshot date specified at § 414.1325.

In the CY 2022 ASC/OPPS proposed rule we proposed to change this policy to be inclusive of new RT providers and RT suppliers that would be required to participate in the RO Model after the start of a PY; we believe this proposal would give all RO participants, including those that begin participation in the RO Model after the start of a PY, more time to review and certify their individual practitioner lists.

We solicited public comments on reviewing and certifying individual practitioner lists. The following is a summary of the public comments received on this proposal and our response:

Comment: We received one comment in support of the proposal to review and certify individual practitioner lists.

Response: We thank this commenter for their support.

We are finalizing as proposed to codify this policy to review and certify individual practitioner lists at our regulation at § 512.217(b).

In the Specialty Care Models final rule, we codified at § 512.217(b) and (c)(1) that the RO participant must review and certify the individual practitioner list within 30 days of receipt of the individual practitioner list. We also codified at § 512.217(d)(1)(i) and (d)(2)(i) that the RO participant must notify CMS within 30 days when there are any additions or removals of eligible clinicians to the individual practitioner list.

In section XVIII.C.7.b of the CY 2022 ASC/OPPS proposed rule, we proposed to modify these policies so that RO participants will have the ability to review their individual practitioner list and add or drop the necessary NPIs from the list up until the last QP determination snapshot date specified at § 414.1325. We proposed to change this policy to give RO participants more time to review and certify their individual practitioner lists by requiring this by the last QP determination snapshot date specified at § 414.1325, instead of within 30 days of receipt of the individual practitioner list (86 FR 42309).

We invited public comments on this proposal to modify the timeframe for which individual practitioner lists shall be certified in the proposed rule.

We received no comments on this proposal (86 FR 42309) and therefore we are finalizing as proposed to codify this policy at our regulation at § 512.217(c)(1) and at § 512.217(d)(1)(i) and (d)(2)(i), and we are finalizing our policy at § 512.217(b) with a non-substantive modification for clarity. We are revising § 512.217(b) for clarity to remove the duplicate use of the term ''certify'' regarding an RO participant's requirement to certify the individual practitioner list.

In the Specialty Care Models final rule, we codified at § 512.217(c)(3) that if Dual participant or Professional participant does not verify and certify the individual practitioner list by the deadline specified by CMS, RO participants on the unverified list are not recognized as participants on a participation list of either a MIPS APM or Advanced APM.

In section XVIII.C.7.b. of the CY 2022 ASC/OPPS proposed rule, we proposed to add at § 512.217(c)(3)(iii) that if individual practitioners who participate in the RO Model with Technical participants that are freestanding radiation therapy centers are not included on a verified list, they would not be eligible to receive Improvement Activity credit under MIPS.

We solicited public comments on this proposal to add § 512.217(c)(3)(iii) in section XVIII.C.7.b of the CY 2022 OPPS/ASC OPPS proposed rule (86 FR 42309).

We received no comments on this proposal and therefore we are finalizing as proposed to codify this policy at our regulation at § 512.217(c)(3)(iii).

c. RO Model Requirements

In the Specialty Care Models final rule, we codified at § 512.220(b) that RO participants must use CEHRT, that the RO participant must annually certify its use of CEHRT during the model performance period, and that the RO participant will be required to certify its use of CEHRT within 30 days of the start of each PY. In CY 2021 OPPS/ASC final rule (85 FR 86262), we amended the CEHRT requirement beginning in PY2, on January 1, 2022, and to be required for PY2 through PY5. However, section 133 of the CAA 2021 prohibits implementation of the RO Model prior to January 1, 2022.

In section XVIII.C.7.c. of the CY 2022 OPPS/ASC OPPS proposed rule, we proposed that the CEHRT requirement would begin in PY1 of the model performance period and that RO participants must certify their use of CEHRT at the start of PY1 and each subsequent PY, as codified at § 512.220(b)(1) and (2). We also proposed to codify at § 512.220(b)(3) that if an RO participant begins participation in the RO Model at any time during an ongoing PY, they would have to certify their use of CEHRT by the last QP determination snapshot date specified at § 414.1325.

In the Specialty Care Models final rule, we codified at § 512.220(a)(1) that RO participants must satisfy the requirements set forth at § 512.220 to qualify for the APM Incentive Payment. In section XVIII.C.7.c. of the CY 2022 OPPS/ASC OPPS proposed rule, we proposed to amend § 512.220(a)(1) to state that RO participants must satisfy the requirements set forth at § 512.220 to be included in Track One of the RO Model. If RO participants do not meet those requirements in a PY, the RO participant would be in Track Two for the applicable PY.

We invited public comments on these proposals related to compliance with the CEHRT requirements and the other requirements as conditions to be included in Track One of the RO Model. The following is a summary of the public comments received on this proposal and our response:

Comment: Many commenters disagreed with the proposal, stating that there is added expense and time required to implement CEHRT. Some commenters recommended that we implement rural or low-volume exemptions to the CEHRT requirement.

Response: We appreciate the commenters' concerns. While we understand the expense and time required to implement CEHRT, we believe that CEHRT is an important element of high-quality care delivery and provides the foundation for improved communication and review of clinical data. We believe that the low-volume opt-out included in the RO Model eliminates the need for an additional low-volume or rural exemption to the CEHRT requirement, and we believe that use of CEHRT is still important in rural areas.

As discussed in section XVII.C.7.a of this final rule with comment period, we are finalizing with modification our proposal to categorize RO participants into three tracks. We believe that the finalized ''Track Two'' RO participant category allows RO participants who do not wish to certify their use of CEHRT to be eligible for MIPS APM reporting and scoring pathways. We believe that this modified policy may lessen the burden of the CEHRT requirement by allowing participants who do not wish or are not able to meet the CEHRT requirement to be eligible for MIPS APM scoring pathways.

Comment: We received many comments noting that the requirements at § 512.220 are burdensome and should be modified or removed because EHR vendors may require additional time to develop fields necessary to capture adherence to the requirements.

Response: We appreciate that the requirements at § 512.220 may require additional effort by RO participants. However, we disagree with the

commenters and do not believe that the requirements will add significant administrative burden as CMS will not require RO participants to report to CMS on these actions with the exception of attesting to the use of CEHRT, the accuracy of their IPL, and participation in a PSO. Rather, compliance with these requirements will be confirmed during virtual and in-person site visits, as described in the Specialty Care Models final rule and codified at §§ 512.130 and 512.150 where CMS may ask for evidence that these requirements are being met. CMS has taken meaningful action to prepare RO participants for the requirements listed at § 512.220. For example, CMS has hosted a webinar on RO Model requirements. Further, as stated in section XII.C.1 of this final rule, we believe that we have provided sufficient time, since the publication of the Specialty Care Models final rule in September 2020, for RO participants and their EHR vendors to implement the software that RO participants may need to adhere to the RO Model requirements. We also note that although an RO participant may document these requirements using their EHR system if they wish, no changes to EHR systems are required for tracking compliance with RO Model requirements. We would also note that how an RO participant tracks their compliance is at their discretion, as long as the RO participant can substantiate their compliance with documentation during a CMS site visit or audit. We are finalizing as proposed to maintain the requirements at § 512.220.

After considering public comments, we are finalizing with modification that RO participants must satisfy the requirements set forth at § 512.220 to be included in Track One of the RO Model. RO participants that meet all of these RO Model requirements in a PY, except for use of CEHRT, will be in Track Two for the applicable PY. RO participants that do not meet one or more of the RO Model requirements in paragraph (a) of this section will be in Track Three for the applicable PY. This policy is codified at § 512.220(a)(1). We are also finalizing as proposed to that the CEHRT requirement would begin in PY1 of the proposed model performance period and that RO participants must certify their use of CEHRT at the start of PY1 and each subsequent PY. This policy is codified at § 512.220(b)(1) and (2). Finally, we are finalizing as proposed that RO if an RO participant begins participation in the RO Model at any time during an ongoing PY, they must certify their use of CEHRT by the last QP determination snapshot date specified at § 414.1325. This policy is codified at § 512.220(c).

8. Reconciliation Process

a. Initial Reconciliation

Reconciliation is the process to calculate reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services. We stated in the Specialty Care Models final rule at 85 FR 61243 that we would conduct the initial reconciliation for PY1 as early as August 2022, and the PY2 initial reconciliation as early as August 2023, and so forth. Given our proposed changes in section XVIII.C.1. of the CY 2022 OPPS/ASC proposed rule to the model performance period (86 FR 42290) which we made in response to the delay under section 133 of the CAA 2021, and our decision to finalize that proposal in section XVII.C.1. of this final rule with comment period, we expect to conduct the initial reconciliation each August for the preceding PY. For example, for PY1, we would conduct the initial reconciliation as early as August of PY2.

In the CY 2021 OPPS/ASC final rule with comment period, we finalized our proposal to amend our regulations at § 512.285(d) such that the quality reconciliation payment amount would not be applicable for PY1, because there would not be a quality withhold in PY1. Proposing to change the model performance period and the application of a quality withhold to begin in PY1 as described in section XVIII.C.5.i. of the CY 2022 OPPS/ASC proposed rule required proposing an amendment to our regulations at § 512.285(d) such that the quality reconciliation payment amount will apply to all PYs.

We solicited public comments on our proposal in section XVIII.C.8.a. of the CY 2022 OPPS/ASC proposed rule (86 FR 42310).

The following is a summary of the public comments received on this proposal and our response:

Comment: Some commenters disagreed with the proposal for the quality withhold to begin in PY1as described and summarized in section XVIII.C.5.i. of this final rule with comment period.

Response: Because we are finalizing our proposals at section XVII.C.6. of this final rule with comment period that quality measures and CDEs will be reported in PY1, we cannot delay the application of the quality withhold in PY1, making the quality reconciliation payment amount applicable to all PYs. The quality withhold allows the RO Model to include quality measure results as a factor when determining payment to RO participants, which is one of the Advanced APM criteria as codified in 42 CFR 414.1415(b)(1).

We are finalizing as proposed that beginning in PY1, a 2 percent quality withhold for the PC will be applied to the applicable trended national base rates after the case mix and historical experience adjustments, and we will codify this policy at § 512.255(c)(10). We are finalizing as proposed that the application of a quality withhold will begin in PY1. Finally, we are amending our regulations at § 512.285(d) such that the quality reconciliation payment amount will apply to all PYs.

b. True-Up Reconciliation

The true-up reconciliation is the process used to calculate additional reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services that are identified after the initial reconciliation and after a 12-month claims run-out for all RO episodes initiated in the applicable PY. We stated in the Specialty Care Models final rule that we would conduct the PY1 true-up reconciliation as early as August 2023, and the PY2 true-up reconciliation as early as August 2024, and so forth (85 FR 61244). We note that this section only involves the removal of the reference to specific years, and, instead, references the specific period of time of ''August of the CY following an initial reconciliation for a PY.'' This allows the text to remain current even if there is a change in baseline period or model performance period. We expect to conduct the true-up reconciliation as early as August of the CY following an initial reconciliation for a PY. For example, for PY1, we would conduct the true-up reconciliation as early as August of PY3.

c. Reconciliation Amount Calculation

We codified at § 512.285(c)(3) that a subset of incomplete episodes in which: (1) The TC is not initiated within 28 days following the PC; (2) the RO beneficiary ceases to have traditional FFS Medicare prior to the date upon which a TC is initiated, even if that date is within 28 days following the PC; or (3) the RO beneficiary switches RT provider or RT supplier before all RT services in the RO episode have been furnished, the RO participant would be owed only what it would have received under FFS for the RT services furnished to that RO beneficiary. CMS will reconcile the episode payment for the PC and TC that was paid to the RO participant with what the FFS payments would have been for those RT services using no-pay claims. Furthermore, we finalized in the case that traditional

Medicare ceases to be the primary payer for an RO beneficiary after the TC of the RO episode has been initiated but before all included RT services in the RO episode have been furnished, each RO participant would be paid only the first installment of the episode payment. The RO participant would not be paid the EOE PC or TC for these RO episodes.

We proposed in section XVIII.C.8.c. of the CY 2022 OPPS/ASC proposed rule to modify this policy such that for all incomplete episodes as defined at § 512.205, including when the RO beneficiary ceases to have traditional FFS Medicare before all included RT services in the RO episode have been furnished, CMS would reconcile the episode payment for the PC and TC that was paid to the RO participant(s) with what the FFS payments would have been for those RT services using no-pay claims. After further reviewing data for incomplete episodes, including incomplete episodes where an RO beneficiary ceases to have traditional FFS Medicare before the end of an episode, we determined that the data did not support paying RO participants only the first installment of an episode for this type of incomplete episode. Upon further review of this data and stakeholder comments on this policy, we proposed in section XVIII.C.8.c. of the CY 2022 OPPS/ASC proposed rule to amend § 512.285(c)(3) and (4) accordingly.

In light of the proposal to modify payment for incomplete episodes, we also proposed conforming changes to § 512.255(c)(12)(iv) regarding beneficiary coinsurance for incomplete episodes. Specifically, we proposed to modify § 512.255(c)(12)(iv) to specify that the coinsurance for all incomplete episodes is 20 percent of the FFS amount applicable to the RT services that were furnished.

We codified at § 512.205 a definition for ''stop-loss reconciliation amount'' to mean the amount owed to RO participants that have fewer than 60 episodes during 2016 through 2018 and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of the Specialty Care Models final rule for the loss incurred under the RO Model as described in § 512.285(f). We proposed to modify the definition for ''stop-loss reconciliation amount'' to mean the amount owed to RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services before the start of the model performance period in the CBSAs selected for participation for the loss incurred under the RO Model as described in § 512.285(f), in order to make this definition consistent with the proposed model performance period.

We solicited public comments on our proposals in section XVIII.C.8.c. of the CY 2022 OPPS/ASC proposed rule (86 FR 42310). The following is a summary of the public comments received on these proposals and our response:

We solicited public comments on our proposal to modify § 512.255(c)(12)(iv) such that for all incomplete episodes as defined at § 512.205, including when the RO beneficiary ceases to have traditional FFS Medicare before all included RT services in the RO episode have been furnished, CMS would reconcile the episode payment for the PC and TC that was paid to the RO participant(s) with what the FFS payments would have been for those RT services using no-pay claims. We received no comments on this proposal.

We solicited public comments on our proposal to specify that the coinsurance for all incomplete episodes is 20 percent of the FFS amount applicable to the RT services that were furnished and to make conforming changes to § 512.255(c)(12)(iv) regarding beneficiary coinsurance for incomplete episodes.

Comment: We received one comment requesting additional information on how RO participants should reconcile beneficiary coinsurance for incomplete episodes in a way that is least burdensome to RO participants and their RO beneficiaries.

Response: We finalized in the Specialty Care Models final rule our proposal to codify at § 512.255(c)(12) a policy that: (1) Permits RO participants to collect beneficiary coinsurance payments for services furnished under the RO Model in multiple installments via a payment plan, (2) prohibits RO participants from using the availability of payment plans as a marketing tool to influence beneficiary choice of health care provider; and (3) provides that an RO participant offering such a payment plan may inform the beneficiary of the availability of the payment plan prior to or during the initial treatment planning session and as necessary thereafter. We believe that this policy places a low burden on RO participants and their RO beneficiaries. We also noted in the Specialty Care Models final rule (85 FR 61199) that RO participants that set up coinsurance payment plans may be able to charge and adjust coinsurance more timely and accurately for incomplete episodes, but in some circumstances the true amount owed by the beneficiary may not be determined until the reconciliation process has occurred.

We are finalizing as proposed to reconcile the episode payment for the PC and TC that was paid to the RO participant(s) with what the FFS payments would have been for those included RT services using no-pay claims and codifying this policy at our regulation at § 512.255(c)(12)(iv).

We solicited comments in section XVIII.C.2. of the CY 2022 OPPS/ASC proposed rule on the definition for ''stop-loss reconciliation amount'' to mean the amount owed to RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services before the start of the model performance period in the CBSAs selected for participation for the loss incurred under the RO Model as described in § 512.285(f).

Comment: Some commenters disagreed with the proposed stop-loss policy as described and summarized in section XVIII.C.5.f of this final rule with comment period.

Response: We responded to these comments in section XVII.C.5.f of this final rule with comment period. As noted in that section, we are finalizing our proposal to modify the stop-loss policy such that those RO participants that had begun furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation are eligible for such a stop-loss limit. Accordingly, as noted in that section, we are finalizing § 512.255(c)(7)(iv) and § 512.205 as proposed. We are also finalizing our proposal to revise the introductory text for § 512.285(f) with one modification, the removal of the word ''any time'' for consistency with § 512.255(c)(7)(iv).

9. Potential Overlap With Other Models Tested Under Section 1115A of the Act and CMS Programs

In the Specialty Care Models final rule (85 FR 61258), we stated that we did not envision that the prospective episode payments made under the RO Model would need to be adjusted to reflect payments made under any of the existing models being tested under section 1115A of the Act or the Medicare Shared Savings Program (Shared Savings Program) under section 1899 of the Act. We also stated that if, in the future, we determined that such adjustments are necessary, we would propose overlap policies for the RO Model through notice and comment rulemaking. However, we did not codify this policy in the regulations for the RO Model at that time. The RO Model is not a total cost of care model, and includes only RT services in the episode payment. The RO Model's payments are narrow in scope because they are limited to RT services furnished during

a distinct period of time. Because the RO Model makes prospective payments for only RT services provided during an episode, a practice participating in the RO Model would receive the same prospective episode payment for RT services regardless of its participation in other CMS models or programs.

Thus, as we noted in in section XVIII.C.9. of the CY 2022 OPPS/ASC proposed rule (86 FR 42310), we continue to see no need to adjust the prospective episode payments made under the RO Model to reflect payments made under the Shared Savings Program or under any other models tested under section 1115A of the Act. We proposed to codify this policy on overlaps at § 512.292. The financial methodology and accounting policies under the applicable model tested under section 1115A of the Act or under the Shared Savings Program will continue to govern the way in which RO Model payments are factored into reconciliation calculations for that initiative. We believe that other initiatives that use a total cost of care approach could consider taking the necessary steps to update their financial methodologies to adjust for the RO Model payments, but we note that the RO Model payments may only be a small portion of the population's overall payments.

We solicited public comments on our proposal to codify our overlap policy in section XVIII.C.9 of the CY 2022 OPPS/ASC proposed rule (86 FR 42310).

We received no comments on this proposal and therefore we are finalizing the proposed new regulation at § 512.292 without modification.

10. Extreme and Uncontrollable Circumstances Policy

The nation, its communities, and its health care providers, on certain occasions, are forced to confront extreme and uncontrollable circumstances (EUC) outside of their control that impact their ability to operate in the ordinary course of business for short-term or sometimes even extended periods. For example, the U.S. has been responding to an the ongoing COVID–19 PHE, which has impacted the U.S. health care system, presenting challenges for stakeholders across the health care delivery system and supply chain. Other extraordinary events that have a disruptive impact may also occur in the future. These events may include other public health emergencies, large-scale natural disasters (such as, but not limited to, hurricanes, tornadoes, and wildfires), or other types of disasters. Such events may strain health care resources, and CMS understands that RT providers and RT suppliers may have limited capacity to continue normal operations and fulfill RO Model participation requirements under such circumstances. Therefore, we proposed to adopt an EUC policy for the RO Model which would allow CMS to revise the model performance period; grant certain exceptions to RO Model requirements to ensure the delivery of safe and efficient health care; and revise the RO Model's pricing methodology.

a. Extreme and Uncontrollable Circumstance Affects the Nation, Region, or a Locale

We proposed in section XVIII.C.10. of the CY 2022 OPPS/ASC proposed rule (86 FR 42311) to define an EUC as a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to deliver care in accordance with the RO Model's requirements, and affects an entire region or locale. We proposed that if CMS determines that there has been an EUC for a geographic region, CMS may: (1) Amend the model performance period; (2) eliminate or delay certain reporting requirements for RO participants; and (3) amend the RO Model's pricing methodology. Application of the modifications would be based on the severity and types challenges that the circumstance imposes on RO participants. In every circumstance, CMS would seek to minimize impact on the RO participants not affected by the EUC, while supporting those that are affected.

In a national, regional, or local event, we proposed to apply the EUC policy only if the magnitude of the event calls for the use of special authority to help providers respond to the emergency and continue providing care. We would not use a bright-line test to assess all types of public health emergencies, disasters, or other extraordinary circumstances; application of the policy would be tailored to the specific circumstance, and to the affected geographic areas. To help identify RO participants that are experiencing an extreme and uncontrollable circumstance, CMS would consider the following factors:

- Whether the RO participants are furnishing services within a geographic area considered to be within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Social Security Act.
- Whether the geographic area within a county, parish, U.S. territory, or tribal government designated under the Stafford Act served as a condition precedent for the Secretary's exercise of the 1135 waiver authority, or the National Emergencies Act.
- Whether a state of emergency has been declared in the relevant geographic area.

In the event that one or more of these conditions are present, CMS would announce that the EUC policy applies to one or more RO participants within an affected geographic area. CMS would communicate this decision via the RO Model website and written correspondence to RO participants.

We solicited public comments on our proposal in section XVIII.C.10 of the CY 2022 OPPS/ASC proposed rule (86 FR 42311). The following is a summary of the public comments received on this proposal and our response:

Comment: We received many comments on the proposed policy. All commenters expressed support for adopting an EUC policy to the RO Model.

Response: We thank commenters for their support.

Comment: Many commenters asked for clarity on how CMS will determine a geographic region or geographic area when determining an EUC. One commenter asked that CMS maintain ample flexibility in defining ''geographic region or geographic area'' and ''state of emergency.'' Many commenters encouraged CMS to maintain ample flexibility regarding how the Agency will define a ''geographic region or geographic area'' and ''state of emergency'' declaration under this proposal in order to address participant-level COVID–19 infection trends, hospitalizations and staffing shortages irrespective of the status of a state or geographic region, as a whole.

Response: We are clarifying that the affected geographic region(s) or geographic area(s) is/are generally identified by state, county, or ZIP Code within the emergency declaration. CMS will identify affected RO participants by ZIP Code just as we did for participation in the Model. ''State of emergency'' is equivalent to the situation described in the emergency declaration including the emergency area and emergency period. If RO participants are concerned that CMS may be unaware of a situation that they believe should qualify for modification under the EUC policy, RO participants could contact the RO Model Help Desk at *radiationtherapy@cms.hhs.gov* with the RO Participant's RO Model ID, a description of the emergency, the affected areas, and the duration of the emergency period included in the declaration. If an emergency exists only in specific geographic areas, the EUC policy would allow CMS to invoke the provisions

related to reporting requirements and other RO Model requirements, and adjust the quality withhold portion of the pricing methodology, for only the affected geographic areas, as described below and finalized at § 512.249.

After consideration of comments received, we are finalizing as proposed our definition that EUC stands for ''extreme and uncontrollable circumstance'' and means a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to deliver care in accordance with the RO Model's requirements, and affects an entire region or locale. We are also finalizing as proposed to codify this definition at § 512.205.

b. Model Performance Period

In instances where an EUC is nation-wide and impacts RO participants' ability to implement the requirements of the RO Model at the start of the model performance period, we proposed that CMS may delay the start date of the model performance period by up to one CY. RO participants would be notified of any changes to the model performance period on the RO Model website no later than 30 days prior to the original start date. In the case where a delay to the model performance period is required because of an EUC, various other aspects of the RO Model may be impacted, including its status as an Advanced APM and the years that would be included in the baseline period. The implications of a model performance period delay on other aspects of the RO Model would also be included in the RO Model website notification no later than 30 days prior to the original start date. In the case of a regional EUC, we did not propose to modify the model performance period, but proposed instead to either delay or exempt RO Model requirements, as discussed in section XVIII.C.10.c. of the CY 2022 OPPS/ASC proposed rule for the RO participants in the impacted region.

We solicited public comments on our proposal in section XVIII.C.10. of the CY 2022 OPPS/ASC proposed rule (86 FR 42311). The following is a summary of the public comments received on this proposal and our response:

Comment: A few commenters asked whether, if we were still in a PHE on January 1, 2022, CMS would use this authority to change any RO Model requirements. Many commenters stated their belief that the current PHE warrants a delay in the start of the model performance period. Many cited the continued rise in Delta variant cases causing delays in cancer surgeries, staffing shortages, and decreased RT services in their comments. One commenter stated their assumption that by including this provision of the EUC policy that CMS would be delaying the start of the model performance period.

Response: We appreciate commenters' feedback on the impact of the COVID–19 PHE on them, and we will consider this feedback in any decisions related to potential EUC flexibilities. We note that there has been another 90-day extension of the current PHE declaration such that the current PHE will overlap with the start of the model performance period, unless the Secretary terminates the PHE before the latest 90-day extension expires CMS will continue to monitor the impacts of COVID–19 on radiation oncology to determine whether the EUC policy may need to be invoked, and if so, which flexibilities to invoke. If and when CMS invokes any of the flexibilities due to an EUC, related to the COVID–19 PHE or otherwise, we will communicate this decision via the RO Model website and written correspondence to RO participants.

Comment: One commenter encouraged CMS to identify in the final rule regions that it intends to declare as EUC regions for the 2022 calendar year, and to develop and conduct monthly reviews of a ''EUC map'' and add new EUC regions should the COVID–19 PHE continue to surge into 2022.

Response: We thank the commenter for the feedback We will take this comment into consideration in the future.

After consideration of the comments received, we are finalizing our proposal that, in instances where an EUC is nation-wide and impacts RO participants' ability to implement the requirements of the RO Model at the start of the model performance period, CMS may delay the start date of the model performance period by up to one CY.

c. Reporting Requirements

Quality Measures and Clinical Data Elements: If an EUC impacts RO participants' ability to comply with the RO Model's quality measure or CDE reporting requirements, we proposed that CMS may delay or exempt the affected RO participants from the reporting requirements, make the requirements optional, extend the time for RO participants to report data to CMS, as applicable, or both. CMS would modify or grant exceptions to the RO Model's reporting requirements if, for example, affected RO participants could not submit their quality and clinical data reporting due to electricity or internet outages caused by an EUC.

Other Model Requirements: Because RO participants must focus on direct care, we proposed that CMS may waive compliance with or adjust the requirement that RO participants actively engage with an AHRQ-listed patient safety organization (PSO) and provide Peer Review (audit and feedback) on treatment plans.

We solicited public comments on our proposal in section XVIII.C.10. of the CY 2022 OPPS/ASC proposed rule (86 FR 42311). The following is a summary of the public comments received on this proposal and our response:

Comment: One commenter encouraged CMS to deploy the EUC policy options related to quality measure and clinical data reporting whenever a given state or region faces a relevant emergency that impacts their patients and staff.

Response: The EUC regulations allow CMS to determine the impact of the EUC on RO participants' ability to comply with the RO Model's quality measure or CDE reporting requirements. CMS may delay or exempt the affected RO participants from the reporting requirements, make the requirements optional, extend the time for RO participants to report data to CMS, as applicable, or both. CMS may modify or grant exceptions to the RO Model's reporting requirements if, for example, affected RO participants could not submit their quality and clinical data reporting due to electricity or internet outages caused by an EUC. If RO participants are concerned that CMS may be unaware of a situation that they believe should qualify for modification under the EUC policy, RO participants could contact the RO Model Help Desk at *radiationtherapy@cms.hhs.gov* with the RO Participant's RO Model ID, a description of the emergency, the affected areas, and the duration of the emergency period included in the declaration.

After consideration of comments we received, we are finalizing as proposed that CMS may delay or exempt the affected RO participants from quality measure and CDE reporting requirements, make the requirements optional, extend the time for RO participants to report data to CMS, as applicable, or both.

We are also finalizing as proposed that CMS may waive compliance with or adjust the requirement that RO participants actively engage with an AHRQ-listed patient safety organization (PSO) and provide Peer Review (audit and feedback) on treatment plans.

d. Pricing Methodology

Adjusting the Quality Withhold: If CMS were to remove (not merely extend) quality and clinical data submission requirements for affected RO participants due to a national, regional, or local event, we proposed that CMS could choose to repay the quality withhold during the next reconciliation, and award all possible points in the subsequent AQS calculation for affected RO participants, which would potentially increase episode payments during this time.

Trend Factor Adjustments: In situations where RO participants nation-wide experience significant, aggregate-level disruptions to their service utilization, in that the trend factor (specific to a cancer type and component) for the upcoming PY has increased or decreased by more than 10 percent compared to the corresponding trend factor of the previous CY when FFS payment rates are held constant with the previous CY, we proposed that CMS may modify the trend factor calculation for the PC and/or TC of an included cancer type.

For example, for PY2, a change in the trend factor calculation for the PC and/or TC of an included cancer type could be warranted if [(2020 volume * 2022 rates)/(2019 volume * 2019 rates)] is more than 10 percent change from [(2019 volume *2022 rates)/(2019 volume * 2019 rates)]. The 10 percent change threshold aligns with the 10 percent criterion for removing an included cancer type, whereby if CMS discovers a ≥10 percent (≥10%) error in established national base rates, the cancer type will be removed from the RO Model. If CMS were to implement this modification, CMS would ensure that the trend factor calculation is most consistent with the average utilization from the previous CY. We proposed to codify the EUC policies at § 512.294.

We solicited public comments on our proposal in section XVIII.C.10. of the CY 2022 OPPS/ASC proposed rule (86 FR 42311). The following is a summary of the public comments received on this proposal and our response:

Comment: Many commenters agreed with the proposal to revise the volume component associated with the trend factor during an EUC to address fluctuations in utilization due to national disruptions in care, such as those caused by COVID–19. Some commenters did not agree with the application of a 10 percent threshold. Instead, these commenters argued that CMS should simply not use the affected year's data and apply the most recent unaffected year's data to the volume component when calculating the trend factor. One commenter noted that during the COVID–19 PHE, treatments have been interrupted or truncated prior to the treatment's completion due to COVID–19 infection. Furthermore, according to the commenter, local quarantine requirements with unknown impacts on patient care could underestimate the true cost of care and true patient volume. Many commenters supported removal of 2020 data from the calculation of any applicable baseline period or trend factor. Some commenters noted that they have experienced a reduction in beneficiaries and a reduction in income in 2020. One commenter noted that businesses on average lost 8 percent of their revenue. A few commenters stated that they are still seeing the impacts of the COVID–19 PHE on their businesses in 2021.

Response: We continue to analyze whether the COVID–19 PHE has significantly changed the utilization and cost patterns within episodes of RT services. We will utilize Medicare claims data to validate concerns about costs and volumes raised by commenters. If this data show that modifications to this policy will be needed due to the ongoing COVID–19 PHE, we will address those modification through future rulemaking.

We believe that so long as there is sufficient evidence, removal of a year's worth of episode data from the trend factor calculation may be warranted. In this case, we believe sufficient evidence constitutes the trend factor (specific to a cancer type and component) for the upcoming PY has increased or decreased by more than 10 percent compared to the corresponding trend factor of the previous CY when FFS payment rates are held constant with the previous CY. An increase or decrease at a lower threshold, such as 5 percent, for example, may remove data that is appropriately reflecting changes in treatment patterns and payment rates that have occurred under OPPS and PFS. We believe that removal of data without sufficient evidence will introduce bias into the Model's pricing methodology.

After consideration of the comments received, we are finalizing as proposed that in situations where RO participants nation-wide experience significant, aggregate-level disruptions to their service utilization, in that the trend factor (specific to a cancer type and component) for the upcoming PY has increased or decreased by more than 10 percent compared to the corresponding trend factor of the previous CY when FFS payment rates are held constant with the previous CY, CMS may modify the trend factor calculation for the PC and/or TC of an included cancer type.

Upon recognition of an omitted phrase in the proposed rule (86 FR 42311), we are finalizing with modification that if CMS were to remove (not merely extend the submission window) quality and clinical data submission requirements for affected RO participants due to a national, regional, or local event, we could choose to repay the quality withhold during the next reconciliation, and award all possible points in the subsequent AQS calculation for affected RO participants, or not apply the quality withhold to RO Model payments during the EUC, which would potentially increase episode payments during this time.

We are finalizing the proposed new regulation at § 512.294 with modification to address the aforementioned omitted phrase and for precision. We are also modifying cross-references at § 512.294(a) for accuracy and precision.

XVIII. Updates to Requirements for Hospitals To Make Public a List of Their Standard Charges

A. Introduction and Overview

1. Statutory Basis and Background

Section 1001 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), amended Title XXVII of the Public Health Service Act (the PHS Act), in part, by adding a new section 2718(e). Section 2718 of the PHS Act, entitled ''Bringing Down the Cost of Health Care Coverage,'' requires each hospital operating within the United States (U.S.) for each year to establish (and update) and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act (the Act). Section 2718(b)(3) of the PHS Act requires the Secretary of the Department of Health and Human Services (Secretary) to promulgate regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for appropriate penalties.

As published in the **Federal Register**, in the final rule entitled ''CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals to Make Standard Charges

Public'' (84 FR 65524, November 27, 2019[570], herein referred to as the CY 2020 Hospital Price Transparency final rule, we implemented these sections by adopting requirements for hospitals to make public their standard charges in two ways: (1) As a comprehensive machine-readable file; and (2) in a consumer-friendly format. We codified these requirements at new 45 CFR part 180.

In the CY 2020 Hospital Price Transparency final rule, we indicated that we believe our policies requiring public release of hospital standard charge information are a necessary and important first step in ensuring transparency in health care prices for consumers, although we also recognized that the release of hospital standard charge information would not be sufficient by itself to achieve the ultimate goals for price transparency. The final regulations were designed to begin to address some of the barriers that limit price transparency with a goal of increasing competition among healthcare providers to bring down costs. In particular, the regulations sought to address the barriers related to lack of hospital standard charge data by requiring some uniformity in the release of hospital standard charge information. We also noted that more work would need to be done to ensure consumers have access to the information they need to make healthcare decisions, and therefore encouraged hospitals and other health care providers to go further in addressing barriers to price transparency.

We received many comments expressing support for or objecting to the policies established and finalized in the CY 2020 Hospital Price Transparency final rule. Issues ranged from CMS's authority to enforce the regulations and assess CMPs, the requirement disclosure of standard charges in a machine-readable format, establishment of payer-specific negotiated charges as a type of standard charge, the burden imposed by the regulation, and other issues unrelated to the policies proposed in the CY 2022 OPPS/ASC proposed rule. We addressed comments on these issues in the CY 2020 Hospital Price Transparency final rule (84 FR 65588) and did not propose in the CY 2022 OPPS/ASC proposed rule to change any of the policies previously established. Accordingly, we consider these comments out of scope.

[570] *https://www.govinfo.gov/content/pkg/FR-2019-11-27/pdf/2019-24931.pdf.*

2. Summary of Final Policies

We are finalizing the following policies in this final rule with comment period: (1) Increasing the dollar amount of penalties for noncompliance through the use of a scaling factor based on hospital bed count; (2) deeming state forensic hospitals that meet certain requirements to be in compliance with the requirements of 45 CFR part 180, and (3) requiring that the machine-readable file be accessible to automated searches and direct downloads. As indicated in the CY 2022 OPPS/ASC proposed rule, we believe these modifications to the hospital price transparency regulations (at 45 CFR part 180) are responsive to stakeholders and are necessary to ensure compliance with the hospital price transparency disclosure requirements. We are also clarifying the expected output of hospital online price estimator tools, where there may be issues with respect to a hospital that chooses to use an online price estimator tool in lieu of posting its standard charges for the required shoppable services in a consumer-friendly format. Finally, we appreciate the thoughtful comments submitted in response to our request for input on a variety of issues that we may consider in future rulemaking to improve standardization of the data disclosed by hospitals.

Comment: While many hospital and hospital associations expressed general support for helping patients know their costs of care, particularly their out-of-pocket costs, such commenters expressed strong concerns that patients will be confused over all the 'tools' available for price transparency, in light of the forthcoming implementation of the No Surprises Act and Transparency in Coverage regulations. These commenters urged CMS to: Ensure alignment across federal transparency initiatives and policies; convene a multi-stakeholder group prior to implementation to ensure alignment across initiatives; and seek input from the public on the information that would be useful for consumers.

Response: We appreciate the commitment expressed by hospitals and hospital associations to improve patient access to and knowledge of their potential out-of-pocket costs and look forward to continued engagement as additional federal price transparency initiatives are implemented. In particular, we appreciate the comments requesting alignment across such initiatives, including those that occur through implementation of the Transparency in Coverage regulations (the TiC Final Rules) and title I (the No Surprises Act) and title II (Transparency) of Division BB of the Consolidated Appropriations Act, 2021 (the CAA).

As the federal government undertakes to implement these new laws and regulations over the next several years, we will continue to monitor and align the Hospital Price Transparency regulations, as necessary. In particular, we note that in the recently published Requirements Related to Surprise Billing; Part II,[571] HHS is seeking comment on how the Hospital Price Transparency requirements for hospitals to display standard charges in a consumer-friendly manner (45 CFR 180.60), and, specifically, the voluntary use of online price estimator tools (45 CFR 180.60(a)(2)), may be leveraged to provide a good faith estimate under the CAA. HHS is also seeking comments on whether there are other opportunities to use the Hospital Price Transparency machine-readable file requirements (45 CFR 180.50) to inform good faith estimates with expected charges, whether or not the comprehensive machine-readable files can assist uninsured (or self-pay) individuals in determining if the good faith estimate charges are reasonable and/or accurate, and what limitations exist in using the comprehensive machine-readable files for purposes of meeting the requirements for provision of the good faith estimates to uninsured (or self-pay) individuals. We encourage the public's continued participation in providing feedback necessary to ensure alignment by responding to the request for comment.

Comment: Many commenters generally welcomed the proposed updates to the Hospital Price Transparency policies and urged CMS to ''make the guidelines for hospitals even stronger.'' Other commenters, hospitals in particular, objected to any modifications for any reason at this time, citing burden imposed by the ongoing COVID–19 PHE.

Response: We appreciate both the general support for the proposals as well as the concerns raised by some commenters. We believe that the proposed modifications are both limited in scope and necessary to ensure compliance with the Hospital Price Transparency final rule and we are therefore finalizing the policies as proposed. Overall, we have also determined that the policies finalized in this rule will result in a burden reduction for hospitals (see Economic

[571] *https://www.federalregister.gov/documents/2021/10/07/2021-21441/requirements-related-to-surprise-billing-part-ii.*

Analysis at XXIV.C.7 of this final rule with comment period).

B. Increasing the Civil Monetary Penalty (CMP) Amounts Using a Scaling Factor

Section 2718(b)(3) of the PHS Act requires the Secretary to promulgate regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for appropriate penalties. In the CY 2020 Hospital Price Transparency final rule (84 FR 65581 through 65590), we established monitoring and enforcement policies at new 45 CFR part 180, subpart C. Specifically, we finalized a process for monitoring hospital compliance with section 2718(e) of the PHS Act, by evaluating complaints made by individuals or entities to the Centers for Medicare & Medicaid Services' (CMS), reviewing individuals' or entities' analysis of noncompliance, and auditing hospitals' websites. Should CMS conclude that a hospital is noncompliant with one or more of the requirements to make public standard charges, CMS may take any of the following actions, which generally, but not necessarily, will occur in the following order:

- Provide a written warning notice to the hospital of the specific violation(s).
- Request a corrective action plan from the hospital if its noncompliance constitutes a material violation of one or more requirements.
- Impose a CMP not in excess of $300 per day, on the hospital and publicize the penalty on a CMS website if the hospital fails to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan.

As described in the CY 2020 Hospital Price Transparency final rule (84 FR 65588 and 65589), we noted that commenters tended to be divided between those in favor of lower and higher CMP amounts, which indicated to us that the proposed (and subsequently finalized) $300 per day amount struck an appropriate balance between commenter concerns. We also noted that this $300 maximum daily dollar CMP amount is lower than CMPs imposed under certain other authorities administered by HHS agencies, where an entity's noncompliance poses immediate jeopardy, results in actual harm, or both, and stated our belief that the relatively lower amount for a CMP associated with a hospital's noncompliance with requirements to make public standard charges was reasonable since such noncompliance is less serious than noncompliance that poses or results in harm to the public.

As discussed in the CY 2020 Hospital Price Transparency final rule (84 FR 65589), we considered commenters' concerns that some hospitals may prefer to forgo meeting the requirements of 45 CFR part 180 (for example, to not expend resources on reporting or to protect pricing information they consider sensitive), and, instead, face compliance actions including a $300 maximum daily CMP amount. Although we declined at the time to increase the amount of the CMP based on this concern alone, we indicated that as we gained experience with implementing the policy we intended to monitor for such occurrences, and may revisit the need to adjust the amount of the CMP in future rulemaking.

We also considered the feasibility of implementing a sliding scale CMP approach across institutions that meet the definition of hospital according to § 180.20 (84 FR 65588 and 65589). However, at the time, we believed it would be challenging to find a reliable source of data that provides for a scalable factor across all institutions that meet the definition of hospital. Therefore, we declined the commenters' suggestions to scale the CMP amount based on such factors as hospital bed size, location or patient volume. However, we indicated that we would continue to consider this issue and might revisit use of a CMP scaling methodology in future rulemaking.

In the CY 2022 OPPS/ASC proposed rule, based on our initial months of experience with enforcing the hospital price transparency requirements in 45 CFR part 180, we expressed our concern by what appears to be a trend towards a high rate of hospital noncompliance identified by CMS through sampling and reviews to date, and the reported initial high rate of hospital noncompliance with 45 CFR part 180 reflected in early studies cited in the proposed rule. One approach we considered to address this trend was to amend the regulations to impose potentially higher CMPs for noncompliance with the hospital price transparency requirements, and to scale the CMP to ensure the penalty amount would be more relevant to the characteristics of the noncompliant hospital. We indicated that we believe that CMPs are an important component in holding hospitals accountable for their noncompliance with hospital price transparency requirements, and would signal the Secretary's continued support for public access to pricing information and enforcement.

Therefore, we considered two general approaches for increasing the CMP amount: (1) A flat increase in the amount that would be applied uniformly across all hospitals, for example, increasing the maximum CMP amount from $300 per day per hospital to $1000 per day per hospital, or (2) a minimum penalty amount and apply a scaling factor (such as bed count or hospital revenue) to increase the penalty in a manner uniquely tailored to the noncompliant hospital. After considering these two general approaches, we proposed to use a scaling factor to establish the CMP amount for a noncompliant hospital.

Several factors informed our proposal to use a scaling factor to determine the CMP amount for noncompliance with hospital price transparency requirements. First, we indicated that this would allow us to penalize a hospital on a sliding scale in a manner that generally correlates to the hospital's characteristics, such as using the hospital's number of beds as a proxy for the size of the patient population it serves. Second, in prior rulemaking, commenters suggested using a scaling factor as an alternative to a uniform CMP amount so as to not overly penalize smaller hospitals, while also providing a sufficient incentive for hospitals to comply. Third, other Federal programs use scaling factors in determining a CMP amount, in particular by taking into consideration the size of the entity subject to the penalty, or calculating the penalty based on the number of enrollees affected.[572] Fourth, since finalization of the CY 2020 Hospital Price Transparency final rule, we have had the opportunity to evaluate and determine a reliable source of data that could be used to establish a CMP amount across most institutions that meet the definition of 'hospital' as defined at § 180.20.

[572] See for example: 42 CFR 3.408(e), specifying factors considered in determining the amount of a civil money penalty include the financial condition of the respondent, including the size of the respondent (among other factors).

45 CFR 160.408(d), specifying factors considered in determining the amount of a civil money penalty include the financial condition of the covered entity or business associate, consideration of which may include but is not limited to the size of the covered entity or business associate (among other factors).

CMS, Civil Money Penalty Calculation Methodology, Revised, June 21, 2019. Available at: *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2019CMPMethodology06212019.pdf* (Pursuant to 42 CFR 422.760(b)(1) and (2), 423.760(b)(1) and (2), 417.500(c), and 460.46, CMS determines if the penalty for a deficiency should be calculated on a per enrollee or per determination basis.).

42 CFR 1003.510 and 45 CFR 102.3, specifying penalty amounts that vary based on number of beds of the hospital; imposing higher penalties for a hospital that has 100 beds or more compared to a hospital that has less than 100 beds.

We also considered the potential specific scaling factor or factors that could be used, and an appropriate data source. We considered two options for a scaling factor: Hospital bed count and hospital revenue. We proposed to use the noncompliant hospital's number of beds, as specified in hospital cost report data submitted to CMS, as the scaling factor to establish CMP amounts. We noted that for purposes of this discussion, we consider ''number of beds'' to be synonymous with ''bed count,'' and that we would use the terms interchangeably.

We indicated we believed the hospital cost report data would be an appropriate data source for a scaling factor for the CMP amount because it is routinely submitted by Medicare-enrolled hospitals, is certified by a hospital official, and is reviewed by a Medicare Administrative Contractor (MAC) to determine acceptability. As explained on the *CMS.gov* website, Cost Reports web page, Medicare-certified institutional providers are required to submit an annual cost report to a MAC. The cost report contains provider information such as facility characteristics and financial statement data. CMS maintains the cost report data in the Healthcare Provider Cost Reporting Information System (HCRIS). HCRIS includes subsystems for the Hospital Cost Report (CMS–2552–96 and CMS–2552–10), among others.[573] Cost Report form CMS–2552–10 and related instructions are effective for hospitals and hospital health care complexes with cost reporting periods beginning on or after May 1, 2010.[574]

For cost reporting purposes, Medicare requires submission of annual reports covering a 12-month period of operations based upon the provider's accounting year. There are also circumstances under which a provider may file a short period cost report for part of a year.[575] Further, there are several exceptions to full cost reporting, including: If a provider does not furnish any covered services to Medicare beneficiaries during a cost reporting period (42 CFR 413.24(g)); or if the provider has had low utilization of covered services by Medicare beneficiaries (as determined by the MAC) and has received correspondingly low interim payments for the cost reporting period (42 CFR 413.24(h)). If the provider fails to submit the cost report, the MAC imposes a penalty by suspending claims payments until the hospital submits the cost report.[576]

The chief financial officer or administrator of the provider certifies the content of the submitted cost report are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions.[577] The MAC reviews the cost report within 30 days of receipt of the provider's cost report to determine acceptability. If the cost report is considered unacceptable, the MAC returns the cost report with a letter explaining the reasons for the rejection. When a cost report is rejected, it is deemed an unacceptable submission and treated as if a report had never been filed.[578] Further, the MAC enters certain data on the hospital cost report into HCRIS, including the cost report status as either: As submitted; Settled without audit; Settled with audit; Reopened; or Amended.[579]

As explained in the CY 2022 OPPS/ASC proposed rule, one of the facility characteristics contained in the cost report is ''number of beds,'' which is the number of beds available for use by patients at the end of the cost reporting period. Specifically, ''[a] bed means an adult bed, pediatric bed, portion of inpatient labor/delivery/postpartum (LDP) room (also referred to as birthing room) bed when used for services other than labor and delivery, or newborn ICU bed (excluding newborn bassinets) maintained in a patient care area for lodging patients in acute, long term, or domiciliary areas of the hospital. Beds in post-anesthesia, post-operative recovery rooms, outpatient areas, emergency rooms, ancillary departments (however, see exception for labor and delivery department), nurses' and other staff residences, and other such areas which are regularly maintained and utilized for only a portion of the stay of patients (primarily for special procedures or not for inpatient lodging) are not termed a bed for these purposes.'' [580]

For Medicare-enrolled hospitals, we proposed to determine the CMP amount using the number of beds for the noncompliant hospital, as specified on the most recently available, finalized cost report data. We anticipate this would be the number of beds for the hospital as indicated in HCRIS as either Settled without audit, Settled with audit, Reopened, or Amended.

We proposed the following approach to scaling the CMP amount based on the hospital's number of beds, and as summarized in Table 76 of this final rule with comment period:

- For a noncompliant hospital with a number of beds equal to or less than 30, the maximum daily dollar CMP amount would be $300, even if the hospital is in violation of multiple discrete requirements of 45 CFR part 180.
- For a noncompliant hospital with a number of beds between 31 and 550, the maximum daily dollar CMP amount would be the number of beds times $10, even if the hospital is in violation of multiple discrete requirements of 45 CFR part 180.
- For a noncompliant hospital with a number of beds greater than 550, the maximum daily dollar CMP amount would be $5,500, even if the hospital is in violation of multiple discrete requirements of 45 CFR part 180.

Therefore, for hospitals with 30 or fewer beds, the CMP amount under the proposed approach would be unchanged compared to the existing policy under § 180.90(c)(2). The proposed use of bed count as a scaling factor would increase the penalty, in some cases significantly, for larger hospitals. The following examples illustrate the proposed approach. A small noncompliant hospital with a bed count of fewer than 30 would be subject to the current CMP amount of $300/day

[573] *CMS.gov*, Cost Reports. Available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports*.

[574] CMS, The Provider Reimbursement Manual—Part 2, publication # 15–2. Chapter 40, Hospital and Hospital Health Care Complex Cost Report Form CMS–2552–10. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935*, Chapter 40—(T16)—Hospital & Hospital Health Care (Form CMS–2552–10) (ZIP), file ''R16P240.pdf'' (herein The Provider Reimbursement Manual—Part 2, Chapter 40). Refer to section 4000, General, 40–7.

[575] CMS, The Provider Reimbursement Manual—Part 2, publication # 15–2. Chapter 1, Cost Reporting—General. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935*, Chapter 1—Cost Reporting General (ZIP), file ''pr2_100_to_140.doc''. Refer to section 102, Cost Reporting Period, 1–3.

[576] 42 CFR 413.20(e). See also, CMS, Hospital and Hospital Health Care Complex Cost Report, CMS Form CMS–2552–10, dated 2020–11–10. Available at: *https://www.cms.gov/regulations-and-guidance legislationpaperworkreductionactof1995pra-listing/cms-2552–10*, CMS–2552–10.zip (ZIP), file ''CMS–2552–10_Supporting_Statement_Part_A.pdf'' (Payment/Gifts to Respondents).

[577] 42 CFR 413.24(f)(4)(iv). See also, Form CMS–2552–10. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935*, Chapter 40—(T16)— Hospital & Hospital Health Care (Form CMS–2552–10) (ZIP), file ''R16P240f.pdf'', Part II—Certification.

[578] 42 CFR 413.24(f)(5)(iii).

[579] The Provider Reimbursement Manual—Part 2, Chapter 40. Refer to Worksheet S—HOSPITAL AND HOSPITAL HEALTH CARE COMPLEX COST REPORT CERTIFICATION AND SETTLEMENT SUMMARY, section 4003.1, Part I—Cost Report Status, Line 5, column 1.

[580] The Provider Reimbursement Manual—Part 2, Chapter 40. Refer to Worksheet S–3—HOSPITAL AND HOSPITAL HEALTH CARE COMPLEX STATISTICAL DATA AND HOSPITAL WAGE INDEX INFORMATION, section 4005.1, Part 1—Hospital and Hospital Health Care Complex Statistical Data, Column 2.

or $109,500/year (that is, 365 days or a full CY of noncompliance). A noncompliant hospital with a bed count of 200 would be assessed a penalty of $2,000/day ($10 * 200/day) or $730,000/year. A noncompliant hospital with a bed count of 550 beds or more would be assessed a maximum penalty of $5,500/day ($10*550/day) or $2,007,500/year.

TABLE 76: Application of CMP Daily Amounts for Hospital Noncompliance for CMPs Assessed in CY 2022 and Subsequent Years.

Number of Beds	Penalty Applied Per Day	Total Penalty Amount for full Calendar Year of Noncompliance
30 or less	$300 per hospital	$109,500 per hospital
31 up to 550	$310 - $5,500 per hospital (number of beds times $10)	$113,150 - $2,007,500 per hospital
>550	$5,500 per hospital	$2,007,500 per hospital

Note: In subsequent years, amounts adjusted according to 45 CFR 180.90(c)(3).

We reviewed CMP amounts for other HHS programs that require reporting information and we believe our proposed maximum daily dollar penalty amount on a sliding scale between $300 and $5,500 per day per hospital is commensurate with the level of severity of the potential violation, taking into consideration that nondisclosure of standard charges does not rise to the level of harm to the public as other violations (such as safety and quality issues) for which HHS imposes CMPs and, therefore, should remain at a relatively lower level. For instance, the proposed maximum amount of $5,500/day, totaling $2,007,500/year would generally align with amounts used by other HHS initiatives that impose CMPs, such as HIPAA-related CMPs that, pursuant to statute, cap penalties at $1.5 million annually.[581]

We proposed that if the number of beds for the hospital cannot be determined according to the most recently available, finalized Medicare cost report data in HCRIS, CMS would use documentation provided by the hospital to determine the number of beds for purposes of calculating the CMP. This approach would be needed to determine the number of beds for a hospital that is not Medicare-enrolled and therefore does not submit to CMS a hospital cost report. Further, we believe there could be circumstances under which there may be an apparent discrepancy, or obvious error, in the most recently available, finalized cost report data for a hospital within HCRIS, and additional documentation from the hospital would be needed to accurately determine the CMP amount.

In the event that CMS requires additional documentation to determine the CMP amount, we proposed to require that the hospital provide CMS with documentation of its number of beds, in a form and manner and by the deadline prescribed by CMS in a written notice provided to the hospital. Should a hospital fail to provide CMS with this documentation, in the prescribed form and manner and by the specified deadline, we proposed that we would impose a CMP on the hospital at the highest, maximum daily dollar amount within the proposed sliding scale. For example, under the proposed approach, if CMS cannot determine a noncompliant hospital's number of beds using hospital cost report data in HCRIS, and if the noncompliant hospital fails to provide CMS with documentation of its number of beds, in the form and manner and by the deadline specified by CMS, we would impose a CMP calculated based on a number of beds greater than 550, and therefore we would impose the maximum penalty of $5,500/day ($10 * 550/day) or $2,007,500/year.

Additionally, we proposed that the approach for scaling the CMP amount based on the hospital's number of beds would apply to days the hospital is out of compliance with hospital price transparency requirements beginning with the effective date of the final rule, assuming the rule is finalized as proposed, and which we anticipate would be January 1, 2022. Further, according to § 180.90(c)(3), the amount of the CMP will be adjusted annually using the multiplier determined by OMB for annually adjusting CMP amounts under 45 CFR part 102. As described in the CY 2020 Hospital Price Transparency final rule (84 FR 65586), this multiplier is based on the Consumer Price Index for All Urban Consumers (CPI–U), not seasonally adjusted. Given that the requirements in 45 CFR part 180, as established by the CY 2020 Hospital Price Transparency final rule, were effective January 1, 2021, and because of the proposed effective date of January 1, 2022, for the modifications to the CMP amounts in the CY 2022 OPPS/ASC proposed rule, we would apply the cost-of-living adjustment multiplier determined by OMB, in calculating CMP amounts for hospital noncompliance with the requirements in 45 CFR part 180, beginning in CY 2023 and subsequent years.

To assist the public in considering the proposals to determine the CMP amount based on the most recently available, finalized number of beds for a hospital indicated in HCRIS, we noted that CMS makes public hospital cost report data in several resources. Data files by fiscal year are accessible through the Cost Reports by Fiscal Year web page, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year*. Specifically, we referred readers to data files by fiscal year (through FY 2020, at the time of the CY 2022 OPPS/ASC proposed rule) for facility type ''HOSPITAL–2010.'' Further, a subset of hospital cost report data for 2014 through 2017 is also made public through the Hospital Cost Report Public Use File web page, available at *https://*

[581] *See* section 1176(a)(3) of the Social Security Act; 45 CFR 160.404.

www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Cost-Report/HospitalCostPUF (providing access to data as either an Interactive Dataset or a Downloadable Excel file).

We sought comment on the proposal to use a sliding scale approach, based on the hospital's number of beds, to determine the CMP amount. In particular, we sought comment on specifying a minimum penalty amount of $300, consistent with the existing CMP amount, for hospitals with 30 beds or fewer, and whether 30 beds is an appropriate number to delineate for this part of the scale. We sought comment on the proposal to impose a CMP of $10/bed/day on hospitals with 31 beds up to 550 beds, including whether we should specify a higher amount to ensure hospitals' compliance with the requirements to make public standard charges. We sought comment on establishing a maximum daily penalty amount of $5,500 for hospitals with more than 550 beds. We also sought comment on our proposal to use hospital cost report data, as specified in HCRIS, to determine bed count, or if we should consider using other validated data sources or files. In particular, we expressed interest in commenters' input on whether there are any available data sources that would encompass relevant scaling data for all hospitals that are subject to the regulations at 45 CFR part 180, including hospitals that are not Medicare-enrolled.

As an alternative approach, we considered using hospital revenue as a scaling factor, instead of or in addition to hospital bed count, as it could more directly take into account the financial burden that a CMP might impose on a noncompliant hospital. For example, we considered using hospital cost report data to determine the noncompliant hospital's annual ''net patient revenues,'' [582] and to calculate a CMP amount as 0.1 percent of hospital revenue, prorated based on the number of days the hospital is out of compliance. That is, we would multiply the revenue amount by 0.001, and then divide the resulting product by 365 to determine the daily CMP amount. Under this alternative approach to scaling the CMP amount based on hospital revenue the minimum penalty applied would remain $300 per day up to a maximum penalty of approximately $5,480 per day, which would continue to generally align with CMPs for issues unrelated to harm to the public. We indicated that if we were we to adopt an approach for using hospital revenue to scale the CMP amount, we would need to address with greater specificity additional factors, including the amount of precision used in the calculations, such as whole dollar amounts, or two decimal place precision. Further, we expressed concern that an approach that uses hospital revenue as a scaling factor for determining the CMP amount may not be as effective as a scaling factor based on bed count in targeting penalties to the size of the hospital, and we noted evidence that suggests that noncompliance is fairly high among larger hospitals.[583] Additionally, we explained that by failing to post the standard charge data, hospitals are directly hindering consumers' decision-making ability, and our belief that the larger the hospital size (as determined by bed count), the more potential patients are impacted, and, thus, our belief that hospital bed count can serve as a more reliable proxy for the number of potential patients that the hospital serves than using net patient revenues. Conversely, application of a penalty based on net patient revenues would increase the penalty for better resourced hospitals compared to those that might have fewer resources. Such an approach may be more effective at deterring noncompliance among better resourced hospitals which may choose not to comply with the hospital price transparency requirements when the financial benefit of noncompliance outweighs a relatively low CMP amount.

In addition to bed size and hospital revenue, we also considered whether and how we could use additional scaling factors for assessing CMPs such as:

- Other financial metrics for scaling the CMP amount, such as using gross revenue, inpatient, or outpatient revenue to establish a penalty amount.
- The nature, scope, severity, and duration of the noncompliance. For example, taking into account the nature and number of deficiencies found upon review, in addition to applying penalties based on the number of days out of compliance.
- The hospital's reason for noncompliance. For example, applying a greater penalty for intentional noncompliance, such as if a hospital states its willful noncompliance on its website or in response to a compliance action from CMS, or application of a lesser penalty that takes into account extreme and uncontrollable circumstances.

We explained in the CY 2022 OPPS/ASC proposed rule that while using multiple scaling factors might have advantages, such as being able to tailor the amount of the CMP to account for unique hospital circumstances and the potential to assess a greater CMP for egregious noncompliance, we did not propose it because we believed we would need additional time and input to ensure that such scaling factors could be applied in a consistent manner across all hospitals that are subject to these regulations. However, we believe such refinements could improve our application of CMPs to promote hospital compliance and therefore sought comment on the following:

- What additional factors would be feasible for scaling a CMP amount?
- What data sources for the criteria could be used to ensure consistency in application of the criteria across all hospitals subject to these regulations? For example, if hospital revenue was used to scale penalties, what data source to determine revenue should be used? For example, are gross income, net income, net patient revenues, or some other metric appropriate for determining burden imposed by a CMP?
- How should nature, scope, and severity of noncompliance be determined and applied for purposes of assessing CMPs?
- How should a hospital's reason for noncompliance be determined? What factors should be considered when evaluating reason for noncompliance? Are there bases for imposing lower CMPs, such as resource limitations or extreme or unusual circumstances? If yes, how could resource limitations or circumstances contributing to noncompliance be demonstrated and should that be treated differently than documented statements of intent to not comply with the requirements?
- If multiple factors are used to scale the CMP amount, should there be a priority applied to specific factors? Should some factors be weighted more when determining the CMP amount? If yes, which one(s)?

We proposed to revise the regulations at 45 CFR 180.90(c)(2) to specify an amended approach for determining the daily dollar amount for a CMP CMS may impose upon a hospital for noncompliance with the requirements in 45 CFR part 180. As conforming changes, we proposed to specify in the regulations at § 180.90(c)(2)(i), the existing approach to determining the CMP amount, as not to exceed $300 per

[582] The Provider Reimbursement Manual—Part 2, Chapter 40. Refer to section 4040.4, Worksheet G–3—Statement of Revenues and Expenses, describing calculation of Net Patient Revenues (subtract Less: Allowance and Discounts on Patient's Accounts from Total Patient Revenue).

[583] Henderson M & Mouslim MC. Low Compliance From Big Hospitals On CMS's Hospital Price Transparency Rule. *Health Affairs*. March 16, 2021. Available at: *https://www.healthaffairs.org/do/10.1377/hblog20210311.899634/full/*.

day, with introductory text specifying the provision is applicable for CY 2021. We proposed to specify in the regulations at § 180.90(c)(2)(ii), provisions for determining the CMP amount for each day a hospital is determined by CMS to be out of compliance beginning January 1, 2022. The CMP amount would be based on the hospitals' number of beds: (A) A maximum daily dollar CMP amount of $300 for hospitals with a number of beds equal to or less than 30; (B) a maximum daily dollar CMP amount calculated as number of beds times $10 for hospitals with a number of beds between 31 and 550; and (C) a maximum daily dollar CMP amount of $5,500 for hospitals with a number of beds greater than 550. We also proposed to specify within § 180.90(c)(2)(ii)(D)(*1*) that CMS would determine the number of beds for a Medicare-enrolled hospital using the most recently available, finalized Medicare hospital cost report. We also proposed to specify within § 180.90(c)(2)(ii)(D)(*2*) the process by which CMS would determine the hospital's number of beds if such information could not be determined using Medicare hospital cost report data. We specify the conditions for CMS' receipt of documentation from the hospital to determine its number of beds, and specify that if the hospital does not provide CMS with such documentation (in the prescribed form and manner, and by the specified deadline), CMS would impose a CMP on the hospital at the highest, maximum daily dollar amount ($5,500 per day). We welcomed comments on these proposals, and the alternatives we considered.

Comment: Many commenters expressed strong support for the proposal to increase civil monetary penalties for noncompliance. Such commenters explained their belief that increased penalties are necessary to ensure hospital compliance so consumers can have access to standard charge information. Many commenters urged CMS to not delay the proposed increase in penalties past the proposed effective date of January 1, 2022, indicating their belief that any delay in enforcement will cause harm to patients, and that compliance is particularly necessary for patients during the COVID–19 PHE.

By contrast, many commenters strongly opposed any proposed methods that would increase penalties for noncompliance. Some commenters indicated their belief that the proposed increase in penalties is misplaced and ''heavy-handed'', given that hospitals may have valid reasons for noncompliance, for example, due to the ongoing COVID–19 PHE or confusion over what is required by the Hospital Price Transparency regulations. Several commenters indicated their belief that it is too early for CMS to conclude there is widespread noncompliance or to determine what effect CMS enforcement has had on improving compliance; at least one commenter asserted that the industry receipt of warning notices from CMS has served to improve compliance and should therefore be viewed as sufficient. Another commenter indicated their belief that the proposal to increase penalties is premature because the regulations and audit process are new to both hospitals and CMS.

These commenters suggested that CMS should, rather than proposing increases to penalties, do the following: Improve the specificity of the requirements; seek to provide technical assistance and guidance; clarify and provide sufficient detail about the enforcement process; clarify how compliance is defined, assessed, and evaluated; publicize results of audits to allow others to learn from the findings; seek to better understand and take into account the reasons for noncompliance; provide ''clearly defined measures that can be obtained and reported across the board by all providers''; and work with hospitals and other stakeholders in an iterative way to improve compliance.

Other commenters made recommendations for delaying enforcement and for delaying the implementation of the new penalties, if finalized. Specifically, commenters recommended enforcement delays: Indefinitely; until enforcement of the No Surprises Act and Transparency in Coverage commences or until the No Surprises Act and Transparency in Coverage policies are aligned with the Hospital Price Transparency rule; or, if proposed increases are finalized, until one full calendar year after the end of the PHE.

Response: We appreciate commenters' support for increasing the civil monetary penalty amounts and for application of a January 1, 2022 effective date as proposed. As indicated in the CY 2022 OPPS/ASC proposed rule, based on CMS' internal analysis of noncompliance, we determined it was necessary to propose an increase in the penalty amount to ensure hospital compliance with the Hospital Price Transparency regulations. Additionally, the CY 2020 Hospital Price Transparency final rule was published in November 2019 and the effective date for compliance was delayed, in response to comments, until January 1, 2021, providing hospitals additional time to prepare for compliance. We believe this delay provided hospitals with sufficient time to collect and display the standard charge information required under this rule. Further, after the Departments finalized the TiC Final Rules (which were finalized a year after the Hospital Price Transparency final rule), Congress enacted title I (the No Surprises Act) and title II (Transparency) of Division BB of the CAA, which impose important new transparency requirements on plans and issuers. As indicated in FAQs About Affordable Care Act And Consolidated Appropriations Act, 2021 Implementation Part 49,[584] the Departments recognize the number of CAA provisions plans and issuers are required to implement by January 1, 2022 and the considerable time and effort required to make the machine-readable files available in the form and manner required in the TiC Final Rules at the same time. Therefore, the Departments are deferring enforcement of some of the TiC Final Rules' requirements. In particular, the Departments are deferring enforcement of the machine-readable file requirements which are more extensive and overlapping with the CAA requirements than the Hospital Price Transparency machine-readable file requirement. We believe that the circumstances surrounding the delay of the TiC Final Rules are not analogous to, and therefore do not warrant, a further delay in the case of the Hospital Price Transparency requirements or its enforcement. As a result, we are finalizing the increased penalties as proposed and decline to delay our enforcement activities or the effective date of the increase in civil monetary penalties for the reasons raised by commenters.

We appreciate the suggestions related to additional actions CMS may take to improve compliance and will consider them for future rulemaking. Commenters seeking clarity related to CMS' assessment can review the regulations at 45 CFR 180.40, 180.50, and 180.60. Commenters seeking clarity related to the enforcement process can review the enforcement process outlined in the regulations at 45 CFR 180 Subpart C—Monitoring and Penalties for Noncompliance. Additional detail for both can be found in the preamble of the Hospital Price Transparency final rule (84 FR 65524). In response to comments related to the need for additional guidance and adequately preparing hospitals, we note

[584] *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf.*

that CMS has engaged in a number of education and outreach activities related to the Hospital Price Transparency regulations, including several Open Door Forums. We continue to encourage hospitals to review the guidance found our dedicated hospital price transparency website (*https://www.cms.gov/hospital-price-transparency*).

We continue to welcome and encourage hospitals and other stakeholders to submit specific questions and concerns to us directly at *PriceTransparencyHospitalCharges@cms.hhs.gov.*

Comment: Regarding the proposed use of bed count to scale civil monetary penalties, many commenters including consumers, consumer advocates, and clinician associations expressed support for increasing CMPs, while several supported specifically the use of bed count as a scaling factor, indicating their belief that such an approach would serve as an effective enforcement measure and ensure consistency and fairness across noncompliant hospitals. One commenter stated their view that the use of bed count would be more meaningful than using a percent of net patient revenue. Two commenters supported use of bed count but recommended that CMS using a ''tiering'' approach rather than a sliding scale approach. Several commenters opposed the proposal to cap the bed count at 550, indicating their belief that the cap should be higher (such as 1000) or uncapped.

One commenter questioned the appropriateness of using bed count as a method of determining a penalty amount because 'most shoppable services . . . have little or no relation to the number of beds in a hospital.' One commenter opposed the 30 bed count minimum, stating that the minimum should be lowered to 25 for consistency with CAH designation.

Many other commenters offered suggestions for alternative approaches or factors that should be used to assess penalties or scale the penalty amount, rather than use of bed count, including: Assessing penalties based on unique hospital characteristics (such as geographic location, rural or critical access designation, nonprofit status, or availability of financial resources) or on a case-by-case basis; phasing in penalties over time; penalties that are based on the scope, nature, or severity of noncompliance, similar to other federal initiatives; refining penalty formulas to ensure ''fairness'' across hospitals; assessment of penalties that take into consideration whether the hospital is demonstrating a good faith effort to comply, has taken actions to address deficiencies, or has communicated with CMS regarding identified issues; penalties that take into account the reason for hospital noncompliance, including any extreme and unusual circumstances, such as the impact of the COVID–19 PHE; and penalties that take into account other hospital price transparency efforts and investments and the burden imposed by the Hospital Price Transparency regulations.

Additionally, many commenters suggested that CMS prioritize certain requirements over others and apply or scale penalties only in cases where hospitals are noncompliant with ''priority'' or ''major'' requirements, and not for ''minor'' infractions or deficiencies. Commenters recommended the following requirements be viewed as priorities: Making public a consumer-friendly display; making public a machine-readable file; making public all five types of standard charges; presence of payer-specific negotiated charges in the machine-readable file; display of all payers and plans with which the hospital contracts; and whether the machine-readable file and consumer display are ''generally complete.''

By contrast, several commenters disagreed with alternative methods for scaling penalties based on factors such as scope, nature, or severity of deficiencies because, as one commenter noted, variability in providers would not permit CMS to scale such penalties equitably. A few recommended CMS consider additional types of penalties such as putting Medicare enrollment status or Medicare reimbursement at risk for noncompliance, or withholding ''federal infrastructure research'' until hospitals become compliant.

Response: We agree with commenters that application of a scaling approach using bed count would be an effective way to ensure compliance, consistency and fairness in application of penalties across noncompliant hospitals. Additionally, as explained in the proposed rule, we believe that use of bed count would allow us to penalize a hospital on a sliding scale in a manner that generally correlates to the hospital's characteristics, and is an appropriate proxy for hospital size and the relative impact a hospital's noncompliance may have on the population, although we acknowledge that this proxy would not necessarily take into account the total number of patients (including outpatients) served by the hospital. However, not all hospitals offer outpatient services, so we believe that use of bed count is an appropriate and consistent factor that could be used across all hospitals subject to the regulation. Moreover, we believe using bed count as a scaling factor takes into consideration the size of the hospital which can help avoid overly penalizing smaller hospitals, such as CAHs.

We appreciate the comments related to the many other factors that could be taken into account to determine the amount of a penalty for noncompliance, including use of alternative penalties. As we explained in the CY 2022 OPPS/ASC proposed rule, use of other or multiple scaling factors might have advantages, such as being able to tailor the amount of the CMP to account for unique hospital circumstances and the potential to assess a greater CMP for egregious noncompliance, however, we continue to decline to include additional factors at this time because we do not believe we have a method to ensure such factors could be applied in a consistent manner across all hospitals that are subject to these regulations. However, we will continue to consider the use of alternative factors and, should we find it necessary to refine the determination of the penalty amount, we will revisit this issue in future rulemaking.

We appreciate the other suggestions made by commenters, including the use of a ''tiering'' approach, but we continue to believe that the scaled approach avoids the cliff effect. We further believe that setting a minimum of 30 beds and maximum of 550 beds is appropriate because the calculated CMP for a hospital with 30 beds or fewer is consistent with the current CMP amount of $300 per day or $109,500 per year (84 FR 65589). Given our experience with compliance, we do not think it is appropriate to lower the CMP amount, and the CMP for a hospital with the 550 or more beds would be approximately $2 million which we believe will provide sufficient incentive for large hospitals to comply with the requirements. However, we will continue to monitor and assess the impact of the minimum and maximum number of beds and may revisit in future rulemaking.

Comment: Several commenters expressed various concerns related to the proposed method for determining the number of hospital beds, and whether the use of Cost Report bed count would be accurate or sufficient for purposes of assessing penalties for noncompliance with 45 CFR 180. A few commenters objected to the use of the Cost Report to identify bed size because the date of submission of the cost report varies and may not reflect an 'official count.' A few commenters requested clarification about what field in the cost

report file would be used to determine bed count. Another commenter suggested that the ''OPPS Hospital Impact File'' would be more user-friendly and requested alignment of the two files such that the bed count used from the Cost Report would be reflected in the OPPS Hospital Impact File, if not already reflected in the ''Number of Beds'' column.

Commenters requested that CMS publish a list of bed sizes annually that would be solely used for CMP assessment for noncompliance with 45 CFR part 180, and provide a mechanism for hospitals to submit corrections within 30 days of the publication of such a list. One commenter suggested using the ''number of licensed beds'' for those that are not Medicare-enrolled and asserted that such an approach would be more equitable and would enable CMS to utilize each state's facilities division information on licensed beds.

Response: We appreciate the comments related to the proposed method for determining hospital bed count via use of the most recently available, finalized hospital cost report. As explained in the proposed rule, we believe the hospital cost report data would be an appropriate data source for a scaling factor for the CMP amount because it is routinely submitted by Medicare-enrolled hospitals, is certified by a hospital official, and is reviewed by a Medicare Administrative Contractor (MAC) to determine acceptability. We therefore believe that use of the hospital cost report is both accurate, official, and sufficient for purposes of assessing penalties for noncompliance with 45 CFR 180 for most hospitals.

As we stated in the CY 2022 OPPS/ASC proposed rule, the field in the hospital cost report we proposed to use to determine bed count is designated as ''number of beds,'' which is the number of beds available for use by patients at the end of the cost reporting period. Specifically, ''[a] bed means an adult bed, pediatric bed, portion of inpatient labor/delivery/postpartum (LDP) room (also referred to as birthing room) bed when used for services other than labor and delivery, or newborn ICU bed (excluding newborn bassinets) maintained in a patient care area for lodging patients in acute, long term, or domiciliary areas of the hospital. Beds in post-anesthesia, post-operative recovery rooms, outpatient areas, emergency rooms, ancillary departments (however, see exception for labor and delivery department), nurses' and other staff residences, and other such areas which are regularly maintained and utilized for only a portion of the stay of patients (primarily for special procedures or not for inpatient lodging) are not termed a bed for these purposes.'' [585] Moreover, because the hospital cost report is readily available to the public, we do not believe it would be necessary to publish a separate list for purposes of assessing penalties for noncompliance with 45 CFR part 180.

We appreciate the suggestion to use and/or modify the ''OPPS Hospital Impact File'' to determine or reflect the number of hospital beds used to assess a penalty amount, however, the OPPS Hospital Impact File [586] gathers and presents bed count data from multiple years of HCRIS data primarily for the purpose of analyzing the impact of the OPPS payment system on hospitals that are paid under that system. While it may draw from the same data set we proposed to use for purposes of determining hospital bed count, we believe using the primary source for such information will be more accurate, complete, and timely than relying on similar data from a secondary analysis. For example, unlike the OPPS Hospital Impact File, the HCRIS primary data set includes the status of the reported information (for example, Settled without audit, Settled with audit, Reopened, or Amended) which we proposed to use to determine the CMP amount using the number of beds for the noncompliant hospital, as specified on the most recently available, finalized cost report data. Additionally, the HCRIS primary data set includes cost reports from all Medicare-enrolled hospitals, unlike the OPPS Hospital Impact File which contains data from only those hospitals paid under the OPPS payment system. We therefore believe that using the primary source (HCRIS) is more accurate, complete, and timely.

Finally, regarding the proposal to use documentation provided by non-Medicare enrolled hospitals for determining the number of beds to be used to assess the CMP amount, we agree with the commenters that each state's facilities division documentation of number of licensed beds could be appropriate for this purpose. As such, if such information is necessary and requested for purposes of assessing a CMP, we would accept documentation of number of licensed beds from a state's facilities division that is provided by non-Medicare enrolled hospitals in the form and manner and by the specified deadline. However, should a hospital fail to provide CMS with this documentation, in the prescribed form and manner and by the specified deadline, we would impose a CMP on the hospital at the highest, maximum daily dollar amount.

Comment: Regarding the proposed $10/bed/day penalty amount, not to exceed $5,500/day, many commenters urged CMS to consider even greater penalty amounts including: increasing the penalty amount to $70/bed/day, $100/bed/day, $300/bed/day or even $1000/bed/day; or increasing the penalty amount to achieve a total penalty of $5 million per year. Such commenters indicated their belief that the proposed increase would remain insufficient to drive hospital compliance and asserted that lack of pricing data amounts to a patient harm issue due to the threat of financial ruin from medical debt. Commenters requested that CMS continue to monitor compliance carefully and signal an intent to increase penalties again in the future should hospital noncompliance persist.

By contrast, others suggested that the penalty should be lower than proposed because they disagreed that noncompliance should be viewed as a patient safety issue, or that it rises to the level of a Health Insurance Portability and Accountability Act of 1996 (HIPAA)-related violation. A few commenters, including rural and critical access hospital advocates, requested that CMS retain the current maximum penalty amount of $300/day instead of proposing $300/day as a minimum penalty amount.

Response: Given the comments, we believe our proposed maximum daily dollar penalty amount on a sliding scale between $300 and $5,500 per day per hospital strikes a good balance and is commensurate with the level of severity of the potential violation. However, we will continue to monitor and assess the impact of this penalty and may revisit in future rulemaking.

Final Policy: We are finalizing, as proposed, a revision to the regulations at 45 CFR 180.90(c)(2) to specify an amended approach for determining the daily dollar amount for a CMP CMS may impose upon a hospital for noncompliance with the requirements in 45 CFR part 180. As conforming changes, we are finalizing, as proposed, to specify in the regulations at § 180.90(c)(2)(i), the existing approach to determining the CMP amount, as not to exceed $300 per day, with

[585] The Provider Reimbursement Manual—Part 2, Chapter 40. Refer to Worksheet S–3—HOSPITAL AND HOSPITAL HEALTH CARE COMPLEX STATISTICAL DATA AND HOSPITAL WAGE INDEX INFORMATION, section 4005.1, Part 1—Hospital and Hospital Health Care Complex Statistical Data, Column 2.

[586] *https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1717-cn.*

introductory text specifying the provision is applicable for CY 2021. We are also finalizing, as proposed, with a technical modification to § 180.90(c)(2)(ii)(B) for clarity, that we will specify in the regulations at § 180.90(c)(2)(ii), provisions for determining the CMP amount for each day a hospital is determined by CMS to be out of compliance beginning January 1, 2022. The CMP amount would be based on the hospital's number of beds: (A) a maximum daily dollar CMP amount of $300 for hospitals with a number of beds equal to or less than 30; (B) a maximum daily dollar CMP amount calculated as number of beds times $10 for hospitals with at least 31 beds up to and including 550 beds; and (C) a maximum daily dollar CMP amount of $5,500 for hospitals with a number of beds greater than 550. We also finalize, as proposed, to specify in § 180.90(c)(2)(ii)(D)(*1*) that CMS will determine the number of beds for a Medicare-enrolled hospital using the most recently available, finalized Medicare hospital cost report. We also finalize, as proposed, to specify in § 180.90(c)(2)(ii)(D)(*2*) the process by which CMS will determine the hospital's number of beds if such information cannot be determined using Medicare hospital cost report data. Specifically, we will specify the conditions for CMS' receipt of documentation from the hospital to determine its number of beds, and specify that if the hospital does not provide CMS with such documentation (in the prescribed form and manner, and by the specified deadline), CMS will impose a CMP on the hospital at the highest, maximum daily dollar amount ($5,500 per day).

C. Deeming of Certain State Forensic Hospitals as Having Met Requirements

Section 180.30(b) of our regulations states that the hospital price transparency requirements at 45 CFR part 180 are not applicable to federally-owned or operated hospitals, including hospitals operated by an Indian Health Program as defined in section 4(12) of the Indian Health Care Improvement Act, and federally owned hospital facilities such as facilities operated by the U.S. Department of Veterans Affairs and Military Treatment Facilities (MTFs) operated by the U.S. Department of Defense. As we explained in the CY 2020 Hospital Price Transparency final rule, we concluded that these exceptions were appropriate because, with the exception of some emergency services, these facilities do not provide services to the general public and their established payment rates for services are not subject to negotiation. Instead, each of these facility types is authorized to provide services to specific populations that meet specific eligibility criteria (84 FR 65532). In addition, federally-owned or operated hospitals such as Indian Health Service and Tribal facilities[587] impose no cost-sharing, or, in the case of VA hospitals[588] and Department of Defense MTFs,[589] little cost-sharing. With respect to such facilities where there is cost-sharing, the charges are publicized through the **Federal Register**, Federal websites, or direct communication, and are therefore known to the populations served by such facilities in advance of receiving health care services. Only emergency services, which would not be shoppable services under our definition because they cannot be scheduled in advance, are available to otherwise non-eligible individuals at federally-owned or operated facilities. Because these hospitals do not treat the general public and their rates are not subject to negotiation, we concluded that it was appropriate to establish different requirements that apply to these hospitals.

In the CY 2022 OPPS/ASC proposed rule, we indicated that we had become aware that some state psychiatric facilities, specifically, state forensic hospitals, may be similarly situated to the types of facilities to which the exception in § 180.30(b) applies and should therefore also be deemed to be in compliance with 45 CFR part 180. Some state forensic facilities are public psychiatric hospitals that exclusively treat patients who are in the custody of penal authorities and who are not responsible for payment for the cost of their care in such facilities which are wholly funded through state general funds.[590] We stated we believed it is reasonable to consider deeming such hospitals as having met the requirements of 45 CFR part 180 for similar reasons that we articulated in the CY 2020 Hospital Price Transparency final rule for deeming federally owned or operated facilities as having met these requirements. Specifically, such state forensic hospitals have specialized patient populations, are not open to the general public, and the rates for such hospital services are not negotiated. Therefore, we proposed to adopt this exception by modifying the introductory language in § 180.30(b) and adding new § 180.30(b)(3) to include state forensic hospitals. For purposes of application of this exception, we proposed to add a definition to § 180.20 to define a ''state forensic hospital'' as a public psychiatric hospital that provides treatment for individuals who are in the custody of penal authorities.[591] Such forensic patients typically include: (1) Offenders incompetent to stand trial, (2) offenders with mental health disorders, (3) mentally ill prisoners transferred from prison, (4) offenders found not guilty by reason of insanity, or (5) post incarcerated civilly committed individuals.[592] In order to be deemed as having met requirements, the state forensic hospital must provide treatment exclusively for individuals who are in the custody of penal authorities (for example, a state psychiatric hospital with a forensic wing would not meet criteria necessary to be deemed to be in compliance). We estimated there are approximately 111 such institutions that could meet the definition of hospital at § 180.20.[593] We proposed to add this exception to § 180.30(b). We welcomed comments on this proposal.

Comment: All commenters that submitted comments on this proposal to deem state forensic hospitals as having met requirements expressed general support. We did not receive any comments opposing the proposal.

Response: We appreciate the support for the proposal to deem state forensic hospitals as having met requirements and are finalizing as proposed.

Comment: One commenter requested that CMS publish a list of all hospitals subject to this deeming requirement.

Response: Many states, which license such institutions as hospitals, maintain this information on publicly available websites, therefore we decline to

[587] Section 1680r(b) of the Indian Health Care Improvement Act (25 U.S.C. 1680r).

[588] VA cost-sharing information available at: *https://www.va.gov/HEALTHBENEFITS/cost/copays.asp*.

[589] MTF cost-sharing information available at: *https://tricare.mil/Costs/Compare* and *https://comptroller.defense.gov/Portals/45/documents/rates/fy2019/2019_ia.pdf*.

[590] Substance Abuse and Mental Health Services Administration, Controlled Expenditures and Revenues for Mental Health Services, State Fiscal Year 2009. Available at: *https://store.samhsa.gov/sites/default/files/d7/priv/sma14≠4843.pdf*.

[591] *CMS.gov*, Psychiatric Hospitals, available at: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Certificationand Complianc/PsychHospitals*.

[592] National Association of State Mental Health Program Directors. Forensic Patients in State Psychiatric Hospitals: 1999–2016. August 2017. Available at: *https://nasmhpd.org/sites/default/files/TACPaper.10.Forensic-Patients-in-State-Hospitals_508C_v2.pdf*.

[593] National Mental Health Services Survey (N–MHSS): 2019, Data On Mental Health Treatment Facilities. Substance Abuse and Mental Health Services Administration. 2020. Available at: *https://www.samhsa.gov/data/report/national-mental-health-services-survey-n-mhss-2019-data-mental-health-treatment-facilities. See Table 3.6.a.*

maintain a separate public list of state forensic hospitals deemed compliant with the hospital price transparency regulations.

Final Policy: We are finalizing, as proposed, the policy to deem state forensic hospitals as having met the requirements of 45 CFR part 180. Specifically, we are finalizing this policy by modifying the introductory language in § 180.30(b) and adding new § 180.30(b)(3) to include state forensic hospitals. For purposes of application of this exception, we are adding a definition to § 180.20 to define a ''state forensic hospital'' as a public psychiatric hospital that provides treatment for individuals who are in the custody of penal authorities.[594] In order to be deemed as having met requirements, the state forensic hospital must provide treatment exclusively for individuals who are in the custody of penal authorities (for example, a state psychiatric hospital with a forensic wing would not meet criteria necessary to be deemed to be in compliance).

D. Improving Access to the Machine-Readable File

Section 2718(e) of the PHS Act requires hospitals to ''make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services.''

As explained in the CY 2022 OPPS/ASC proposed rule, 45 CFR 180.50 requires a hospital to make public its standard charges in a single machine-readable file. Section 180.50(d)(1) of our regulations gives a hospital discretion to choose a website for purposes of making its standard charge information available to the public in the machine-readable file. Section 180.50(d)(2) through (5) set forth our accessibility requirements for this information, including that the standard charge information must be displayed prominently and clearly identify the hospital location with which it is associated; easily accessible, without barriers, including but not limited to being free of charge, without having to establish a user account or password, and without having to submit personal identifying information (PII); and contained in a digital file, within which the standard charge information is digitally searchable.

As discussed in the CY 2020 Hospital Price Transparency final rule, we believe there is a direct connection between transparency in hospital standard charge information and having more affordable healthcare and lower healthcare coverage costs (84 FR 65526). For purposes of displaying all standard charges for all items and services in a comprehensive machine-readable file, we proposed and finalized requirements for the file format, the content of the data in the file, and how to ensure the public could easily access and find the file. We acknowledged that the machine-readable file would contain a large amount of data; however, we indicated that we believe that a single data file would be highly useable by the public because all the data would be in one place. By ensuring accessibility to all hospital standard charge data for all items and services, we stated these data would be available for use by the public in price transparency tools, to be integrated into EHRs for purposes of clinical decision-making and referrals, or to be used by researchers and policy officials to help bring more value to healthcare.

As explained in the CY 2022 OPPS/ASC proposed rule, in our experience, many publicly available web pages that are selected by hospitals to host the machine-readable file (or a link to the machine-readable file) are discoverable using simple internet searches (using key words such as the hospital name plus 'standard charges,' 'price,' or 'machine-readable file') or, for example, by navigating to the hospital's home page and clicking and searching through pages related to patient billing and financing. We noted that because of the flexibility we allowed to hospitals to choose the internet location, we recognized and expected that there would be some variability in how hospitals choose to publicly display their machine-readable file and how quickly the file can be found by the public. However, we indicated our belief that this flexibility is afforded under the regulation so long as the hospital ensures that the machine-readable file is accessible ''without barriers,'' including that the file and its contents would be digitally searchable (84 FR 65561 through 65562).

In the CY 2022 OPPS/ASC proposed rule, we expressed our concern that, in some cases, it appears that hospitals have made standard charge data available online but embedded it in websites without any ability for users to easily or directly download a ''single machine-readable file.'' In other cases, hospitals have posted a link to a single machine-readable file but have, either intentionally or unintentionally, placed barriers that make it more challenging for the public find and access the file and its contents. We cited examples of such activities and practices including:

- Employing common methods that hinder the findability [595] of a web page that contains a link to the machine-readable file, such as through the use anti-automation tools such as form submission, or other technological devices that place a ''locked door'' in front of the content thereby making it difficult or impossible for search engines to identify the data. There have also been reports of hospitals using ''blocking codes'' such as use of NOINDEX and ''rel canonical'' tagging or disallow statements or removing the URL from the search index through the use of the webmaster tools URL removal service. These techniques prevent commonly used web search engines from caching web pages on which the link to machine-readable files reside.[596] These examples of tools and codes present barriers because they limit the public's ability to easily search for and find the web page that hosts a link to the machine-readable file.
- Employing common methods that prevent direct access to the file and its contents. For example, some hospitals implement anti-automation tools such as requiring users to pass tests proving they are human users prior to accessing the file, for example, the implementation of CAPTCHA and reCAPTCHA in web applications. CAPTCHA stands for ''Completely Automated Public Turing test to Tell Computers and Humans Apart.'' Common CAPTCHA and reCAPTCHA mechanisms may include distorted text inside images, where the user has to type the text or nine or sixteen square images, where the user has to identify the images that contain certain objects, such as vehicles, trees, or street signs. In other instances, some hospitals require the user to take additional actions upon clicking the link to the machine-readable file, prior to download. For example, pop-up windows that require the user to agree all terms and conditions in a legal disclaimer prior to permitting the machine-readable file and its contents to be downloaded. Such pop-up windows do not permit direct access to the file and its contents, and present a barrier.
- Developing file constructs and web forms that obscure access to the data in

[594] CMS.gov, Psychiatric Hospitals, available at: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/PsychHospitals.*

[595] Fishkin R. 12 Ways to Keep Your Content Hidden from the Search Engines. *Moz.* January 15, 2008. Available at: *https://moz.com/blog/12-ways-to-keep-your-content-hidden-from-the-search-engines.*

[596] McGinty T, et al. Hospitals Hide Pricing Data from Search Results. *The Wall Street Journal.* March 22, 2021. Available at: *https://www.wsj.com/articles/hospitals-hide-pricing-data-from-search-results-11616405402.*

a single machine-readable file through the use of Application Programming Interfaces (APIs). For example, we have found APIs that use calls for data that will not return a complete data file, that do not provide supporting documentation on the use of the API to retrieve the file, and that do not allow a single query to return all data in a single machine-readable file. These APIs control access to the data in a way that prevents or conceals access to the entire data file. As such, these types of APIs present barriers to direct access to a 'single machine-readable file' and are therefore not permissible forms of APIs for use by a hospital.

Given this additional experience, we proposed to amend the regulations by adding paragraph (d)(3)(iv) to § 180.50 to specify that the hospital must ensure that the standard charge information is easily accessible, without barriers, including, but not limited to, ensuring the information is accessible to automated searches and direct file downloads through a link posted on a publicly available website. We indicated our belief that this additional requirement would ensure greater accessibility to the machine-readable file and its contents and would prohibit practices we have encountered in our compliance reviews, such as lack of a link for downloading a single machine-readable file, using ''blocking codes'' or CAPTCHA, and requiring the user to agreement to terms and conditions or submit other information prior to access.

We sought comment on whether stakeholders have identified additional barriers that we should prohibit. We noted that the list of examples of barriers we have encountered in our reviews of hospital websites is not intended to be exhaustive, and that should we identify additional barriers that prevent automated searches or direct download of the machine-readable file, we may prohibit them via, as appropriate, guidance or future rulemaking.

Finally, we sought comment on whether there are specific criteria we should consider when evaluating whether a hospital has displayed the machine-readable file in a ''prominent manner.'' We explained our belief that files that are posted in a prominent manner can reduce public burden for searching and finding the files, and can ensure the public can easily find the machine-readable file and the information contained within it. When files are posted prominently, we noted, we would be able to more easily monitor and assess hospital compliance with the CY 2020 Hospital Price Transparency final rule. For example, we indicated we were considering establishing a more standardized approach for how hospitals would be required to make public the machine-readable file, in order to relieve the burden on the public and ensure files are found easily. One such method could be to require hospitals to post their machine-readable files using a CMS-specified URL, in addition to the CMS-specified naming convention. Another approach could be to require a standardized location for hospitals to post a link to the file from the hospital's homepage, thus limiting the public's search for such files to the homepage of the hospital and relieving burden on the public to spend time searching for the file. We sought comment on these methods for ensuring that the machine-readable files posted are prominently displayed and easily accessible.

Comment: Many commenters expressed general support for removal of any and all barriers to access. Commenters strongly supported the current accessibility requirements (specifically, that the information be accessible free of charge, without having to establish a user account or password, and without having to submit personal identifying information) and urged CMS to finalize the additional proposed requirement that the machine-readable file be accessible ''to automated searches and direct file downloads through a link posted on a publicly available website.'' Commenters stated that the proposed rule's examples of activities that present barriers to access are accurate and expressed their belief that such a policy is ''necessary, important, and worthwhile'' to improve public access to machine-readable files. Commenters noted that by employing such strategies, hospitals are engaging in additional and unnecessary work, and suggested that the self-imposed additional burden reflects an active intent on the part of a hospital to obfuscate the data and new regulations. Additionally, some commenters expressed appreciation for the specific examples cited by CMS in the proposed rule and urged CMS to continue to provide this type of guidance to help hospitals comply with the new rules.

By contrast, many commenters requested that CMS not impose any additional requirements on hospitals at this time. Instead, commenters recommended that CMS: Identify practices that support access and allow hospitals flexibility to tailor different strategies to their own organizational goals; improve education and outreach; and not impose requirements that would increase hospital administrative costs to comply and 'redevelop' their price transparency solutions.

Several commenters objected to the proposal because ensuring the machine-readable file is accessible to direct downloads from a link posted on a web page would prohibit the use of certain activities and methods such as the use of pop-up disclaimers and agreements as a prerequisite to accessing the machine-readable file. Commenters asserted that pop-up disclaimers are necessary because the information in the machine-readable files could be confusing or even misleading to consumers if presented without context or explanation, and that pop-up disclaimers ''are the only protection hospitals have to avoid negative consequences of misinterpreting information.'' Additionally, commenters argued that CMS itself encouraged use of disclaimers, citing the Hospital Price Transparency final rule in which CMS encouraged hospitals to include ''appropriate disclaimers in their price estimator tools'' (84 FR 65579). Commenters indicated their belief that hospitals can properly require that a consumer acknowledge the hospital's disclaimers through pop-ups without compromising the accessibility of the machine-readable file.

A few commenters objected to the requirement to ensure direct download of the machine-readable file because it would prevent using methods such as CAPTCHA which, commenters asserted, is necessary for hospitals to safeguard the overall web-based hosting environment. Commenters explained that due to the size of some of the files, repeated automated attempts by external sources could place stress on the bandwidth of hospital networks and could present as a ''denial of service'' attack. Denial of service attacks, in turn, could result in the shutdown of the website and interrupt patient access to the website. Commenters recognized there are mitigation strategies available to hospitals, but that some such strategies may represent an additional cost to the facility to implement. Additionally, commenters pointed out that the federal government uses CAPTCHA on some websites for certain purposes, such as the submission of public comment to proposed rules on the **Federal Register** site.

One commenter objected to requiring direct access to the machine-readable file through a link posted on the web page because such a requirement would prohibit the ability to use other methods for displaying standard charge information, such as the use of APIs. Commenters asserted that use of APIs should be permitted because machine-

readable file information that is searchable through an API is beneficial to the end-user. This commenter asserted that finalizing the proposal would increase burden because hospitals using APIs in lieu of providing the public with access to a single machine-readable file may require some hospitals to redevelop their price transparency solutions.

Response: We appreciate and agree with commenters that additional criteria are necessary at this time to ensure public access to the information in the machine-readable file. We believe that prohibiting practices that prevent automated access and direct downloads permits greater flexibility than prescribing the way a hospital must support access. Although we recognize, as articulated by commenters, that there may be legitimate reasons why a hospital may have chosen to display its data the way it currently does, we nonetheless believe the employment of such practices articulated in the proposed rule present barriers to access to the information in the machine-readable file and are thus finalizing the policy as proposed. Any such practice that prevents accessibility of the machine-readable file via automated searches and direct file downloads would be prohibited under this final rule.

We continue to believe that pop-ups (including pop-up disclaimers) present a barrier to both automated and manual access to the machine-readable file by preventing direct download of the file via a link on the hospital's web page. We do not believe, as suggested by some commenters, that such pop-up disclaimers are the only protection afforded to hospitals to avoid negative consequences of misinterpreting the information contained in the machine-readable file. Even so, we note that this prohibition would not prevent a hospital from providing any additional information or relevant disclaimers in the machine-readable file itself or on the web page containing the link to the machine-readable file. However, under the new requirements, such disclaimers or explanatory information may not be used as a barrier to direct downloads of the file from a link on the hospital's web page. Additionally, we do not believe that the policy to require direct downloads is inconsistent with our encouragement of the use of disclaimers in price estimator tools because such tools are designed specifically for manual use by an individual, in contrast to a display of data that is intended to be widely accessible, including accessible by machines. Moreover, we have not received complaints that pop-ups (including pop-up disclaimers) are creating a barrier to access to price estimator tools. However, we will monitor this issue and, to the extent that CAPTCHA or pop-ups (including pop-up disclaimers) present a barrier to access to price estimator tools, we may address it in future rulemaking.

We agree with commenters who indicated that prohibiting use of CAPTCHA (and other similar barriers to directly downloading the machine-readable file) will increase the usability of the machine-readable file for the public, including for researchers and others who seek to update their data sources as part of an automated process. We acknowledge that some commenters may have concerns related to bandwidth considerations and server security. We note, however, that access to machine-readable files from websites is not unusual, nor are direct downloads. Moreover, accounting for bandwidth considerations and preventing attempted denial of service attacks is within the scope of routine server administration. Server administrators therefore have mitigation strategies to address both issues. For example, in our compliance reviews, we have noticed that some hospitals have employed alternative hosting or caching of the machine-readable file. We note that the regulations related to location and accessibility of the machine-readable file require hospitals to ''select a publicly available website for purposes of making public the standard charge information'' (45 CFR 180.50(d)). Thus, hospitals have flexibility to determine the most appropriate public website for posting that permits the public access to the machine-readable file in accordance with the requirements of the final rule. We believe that hospitals can carefully consider how to display the link to the machine-readable file such that all requirements for posting may be met.

We disagree with commenters that suggest that we should not finalize the policy as proposed because some federal websites, such as the **Federal Register**, use CAPTCHA for submission of comments. Use of CAPTCHA for purposes of comment submission to the **Federal Register** is a fundamentally different process than the process for downloading a static file. In the comment response process, the CAPTCHA helps to prevent automated data submission, thereby protecting the value of the comments received by the federal government by ensuring the content submitted is user-created. When downloading a static file, no user-created content is submitted to a web server and therefore there is no data to protect. A more appropriate comparison than the comment submission process to the **Federal Register** would be public access to information that can be downloaded from *Data.gov* which allows the public to directly download data files; Data.gov does not have CAPTCHA requirements or other impediments for accessing direct data downloads.

In the CY 2020 OPPS/ASC proposed rule (84 FR 39582 through 39583), we specifically sought comment on adopting a requirement that hospitals use an open standards-based API through which they would disclose their standard charges and associated data elements. Ultimately, we finalized a policy for hospitals to make public their standard charges by posting a single machine-readable file online as a good initial step, while indicating that as hospital disclosure of standard charges matures, we intended to revisit the issue. Thus, while hospitals are not prohibited under the final rule from making public standard charges via API technology, or using such technology for a consumer-friendly display of standard charges, hospitals must still make public their standard charges in a single machine-readable file. Under this finalized accessibility policy, such single machine-readable files must additionally be accessible to automated searches and direct file downloads through a link on the hospital website.

Comment: Some commenters noted that the most pressing barrier to access is the lack of hospital compliance with the Hospital Price Transparency regulations. Others outlined various technical challenges in identifying and searching for the location of the file related to website domain names, hospitals that don't maintain websites, and search results that include links to third party aggregators of the files. Several commenters requested more guidance related to what is acceptable to meet the current 'prominently displayed' requirement. Others provided detailed suggestions for improving future requirements related to file 'findability,' including: Consideration for developing a centralized location for hospitals to either make public the machine-readable file or to submit a link to the machine-readable file's location; requiring use of certain searchable words or terms on the web page that contains the link to the machine-readable file; requiring hospitals to place a link to the file (or its web page) on the hospital's homepage; requiring the file to be on a web page that is no more than two clicks from the hospital's homepage; requiring hospitals to locate the file on a dedicated price

transparency web page on the hospital's own website. Several commenters supported the establishment of a CMS-specified URL, although one commenter noted that this would not be necessary if CMS chose instead to establish and enforce a specific location for the link to the machine-readable file.

By contrast, other commenters supported the current flexible approach and objected to more specificity in file location requirements, other than ensuring the file is 'not blocked from public view.' One commenter noted that hospitals have frequently chosen to post the link to the machine-readable file on the hospital billing web page.

Response: We appreciate the feedback and acknowledge that hospitals may be experiencing technical challenges as they implement the hospital price transparency requirements. As noted above, we will continue to educate hospitals about the requirements, including the requirement to use the CMS-specified naming convention. Regarding the request for additional guidance related to how a hospital should ensure that the machine-readable file is displayed 'prominently,' we refer hospitals to the detailed discussion in the CY 2020 Hospital Price Transparency final rule (84 FR 65561) (84 FR 65561). In response to commenters requesting additional guidance for how to ensure their machine-readable files are 'prominently displayed', we recommend hospitals do the following:

- Review and use, as applicable, the HHS Web Standards and Usability Guidelines (available at: *https://webstandards.hhs.gov/*), which are research-based and are intended to provide best practices over a broad range of web design and digital communications issues.
- Post a link to machine-readable file on a website where the value and purpose of the web page and its content is clearly communicated, for example, a dedicated price transparency web page or a web page devoted to patient billing or financing healthcare services.
- While ''breadcrumbs'' (for example, secondary navigation aids) can be useful for navigating a website, they should not be relied upon in order for consumers to find the link to the machine-readable file. Instead, facilitate user navigation by including searchable terms on the web page such as ''price transparency,'' ''standard charges,'' or ''machine-readable file.''
- Ensure that the link to the machine-readable file is visually distinguished on the web page, and that its purpose is to open the single machine-readable file for a clearly indicated hospital location.

Additionally, we appreciate the detailed comments related to challenges in locating files, and will continue to consider these suggestions for future rulemaking.

Final Policy: We are finalizing, as proposed, an amendment to the regulations by adding paragraph (d)(3)(iv) to § 180.50 to specify that the hospital must ensure that the standard charge information is easily accessible, without barriers, including, but not limited to, ensuring the information is accessible to automated searches and direct file downloads through a link posted on a publicly available website. We believe that this additional requirement will serve to ensure greater accessibility to the machine-readable file and its contents and would prohibit practices we have encountered in our compliance reviews, such as lack of a link for downloading a single machine-readable file, using ''blocking codes'' or CAPTCHA, and requiring the user to agreement to terms and conditions or submit other information prior to access.

E. Clarification and Requests for Comment

1. Clarification of the Price Estimator Tool Option

In the CY 2022 OPPS/ASC Proposed Rule, we indicated that we had previously finalized a requirement that hospitals make public certain standard charges for 300 ''shoppable'' services in a consumer-friendly manner. We very briefly summarized the rationale and policy finalized in the CY 2020 Hospital Price Transparency final rule at § 180.60(a)(2) that a hospital may voluntarily offer an internet-based price estimator tool and thereby be deemed to have met our requirements to make public its standard charges for selected shoppable services in a consumer-friendly manner, so long as such a price estimator tool:

- Provides estimates for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services.
- Allows healthcare consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service.
- Is prominently displayed on the hospital's website and be accessible without charge and without having to register or establish a user account or password.

In the CY 2022 OPPS/ASC proposed rule, we clarified that to satisfy our requirement at § 180.60(a)(2)(ii), a price estimator tool ''[a]llows healthcare consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service''. Moreover, such a price estimator tool must be ''tailored to individuals' circumstances (whether an individual is paying out of pocket or using insurance) and provide real-time individualized out of pocket estimates that combines hospital standard charge information with the individual's benefit information directly from the insurer, or provide the self-pay amount.'' (84 FR 65578) [597] We went on to note our concern that our reviews of hospital compliance have identified that some hospital price estimator tools do not tailor a single estimated amount based on the individual's circumstance, but, instead, provide estimated average amounts or ranges for the price of a shoppable service that appear to be generated based on a broad population of patients, including outliers. Others do not appear to combine hospital standard charges with the individual's benefit information directly from the insurer to create the estimate, but instead, appear to use information from prior reimbursements or require the user to input benefit information. Still others appear tailored to the individual, but indicate that the price is not what the hospital anticipates that the individual would be obligated to pay, even in the absence of unusual or unforeseeable circumstances. We stated in the proposed rule that such price estimator tools would therefore fail to satisfy our requirements at § 180.60(a)(2).

We noted that under the CY 2020 Hospital Price Transparency final rule, hospitals are not required to offer online price estimator tools. However, we emphasized that when a hospital chooses to offer an online price estimator tool as an alternative to presenting its standard charge information in a consumer-friendly format, we believe it is important for the hospital to select and offer a price estimator tool that provides a single dollar amount that is tailored to the individual seeking the estimate, taking

[597] There were several typographical errors in the clarification published in the proposed rule. The sentence should read as follows: Moreover, such price estimator tools must be tailored to individuals' circumstances (whether an individual is paying out-of-pocket or using insurance) and provide ''real-time individualized out-of-pocket estimates'' that ''[combines] hospital standard charge information with the individual's benefit information directly from the insurer'', or provide the self-pay amount. (84 FR 65578)

the individual's circumstances into consideration when developing the estimate. Moreover, we stated that the estimate must reflect the amount the hospital anticipates will be paid by the individual for the shoppable service, absent unusual or unforeseeable circumstances. We also emphasized that nothing in the Hospital Price Transparency regulations would preclude a hospital from providing additional information that may be helpful to the consumer, such as a range of prices paid by a defined population of consumers for the item or service in the past, or informing the inquirer what circumstances could change the personalized estimate.

Finally, we indicated that we were considering whether we should add requirements for the use of an online price estimator tool as an alternative to making public the standard charges for shoppable services in a consumer-friendly format. We sought stakeholder input for future consideration related to the price estimator tool policies, including identifying best practices, common features, and solutions to overcoming common technical barriers, and specifically, sought input on:

- What best practices should online price estimator tools be expected to incorporate?
- Are there common data elements that should be included in the online price estimator tool to improve functionality and consumer-friendliness?
- What technical barriers exist to providing patients with accurate real-time out-of-pocket estimates using an online price estimator tool? How could such technical barriers be addressed?

Comment: Many commenters supported the policy finalized in the Hospital Price Transparency final rule to permit use of price estimator tools that ''[a]llows healthcare consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service,'' in lieu of making public standard charges in a consumer-friendly manner at 45 CFR 180.60. A few commenters urged CMS to go further and permit such tools to satisfy the requirements for all hospital price transparency rules, including the machine-readable file requirements at 45 CFR 180.50. By contrast, many commenters expressed concerns with permitting hospital use of price estimator tools for any purpose, including meeting the consumer-friendly display requirements at 45 CFR 180.60, because they believe that hospitals are using such tools to continue to obfuscate and avoid making public their standard charges, as required by the law and in accordance with the Hospital Price Transparency final rule. Such commenters explained that consumers want knowledge of 'real' prices, including standard charges, and not just their final out-of-pocket obligations. Commenters asserted that full disclosure of the inputs to determine the out-of-pocket costs are necessary for consumers to validate the final bill. A few commenters therefore urged CMS to rescind the flexibility afforded in the rule that allows hospitals to voluntarily offer price estimator tools that offer only out-of-pocket estimates instead of making public their standard charges for shoppable services in a consumer-friendly manner.

Many commenters, including several providers and provider organizations, expressed strong support and agreement with the clarification that price estimator tools must take into consideration the individual's insurance information when providing an out-of-pocket estimate. Commenters stated that such tools are routinely in use in hospital systems around the country and provide meaningful and accurate estimates to consumers of their out-of-pocket obligations. Others noted that since finalization of the Hospital Price Transparency final rule, the adoption of such real-time tools has increased, along with vendor support for price estimator tools that take individuals' payer information into account. One commenter noted that regular communication channels between both payers and their estimation tool vendor had proven to be a valuable best practice to address estimation accuracy issues.

A few commenters strongly disagreed with the clarification. One commenter objected to requiring that, in order to qualify for an exception to 45 CFR 180.60(b) through (e), a price estimator tool must use a 'standard-charges-based' methodology to provide an estimate of a patient's expected cost sharing obligation. This commenter stated that such a requirement would unduly limit a hospital's flexibility without benefitting consumers. Two commenters pointed out that a statement attributed as a quote from the Hospital Price Transparency final rule (specifically the quote attributed to 84 FR 65578) could not be found and therefore invalidates the clarification. One of the commenters noted that the sections of the quote are contained in separate sections of the Hospital Price Transparency final rule but that the combined quote does not exist. Both commenters suggested that the clarification is contradictory because the Hospital Price Transparency final rule indicates that hospitals should advise user to ''consult, as applicable, with his or her health insurer to confirm individual payment responsibilities and remaining deductible balances.''

Several commenters disagreed that the examples we provided in the proposed rule of price estimator tools would be considered noncompliant, including the following that would be considered out of compliance:

- Tools that provide estimated amounts or ranges, instead of a single dollar out-of-pocket amount. Commenters asserted that ranges are useful to consumers.
- Tools that use prior claims to estimate the potential total standard charges. A commenter asserted that past claims, properly used, can provide a more accurate basis for establishing a reasonable estimate than the use of standard charges. Another indicated that it is impractical to load the information from all payers and all plans and therefore some amount of averaging is necessary.
- Tools that do not combine hospital standard charges with benefit information directly from the insurer, requiring the user to input their own benefit information. Some commenters indicated that some tools request benefit information to be submitted by the consumer, explaining not all payer information is available electronically or updated frequently enough. One commenter noted that, in order to provide more meaningful and accurate estimates, some hospitals have developed an option for patients to manually input or override certain information, such as their progress toward meeting a deductible. Some commenters noted that each electronic transaction with the payer may result in a transaction fee borne by the hospital. Another indicated that electronic requests do not consistently return necessary information from the payer.
- Tools that indicate the price is not what the hospital anticipates the individual would be obligated to pay, even in the absence of unusual or unforeseeable circumstances. One commenter requested that CMS clarify that 'unusual and unforeseen circumstances' are not the only reasons that a final cost could deviate from an estimate because some patient needs are unknowable but not unforeseen; for example, having to order lab tests may not be unusual or unforeseen, but it may not be known in advance which exact labs will be needed. Others requested that CMS enforce the requirement that the price estimator tool reflect the amount that the individual would be ''obligated'' to pay as a binding and

guaranteed estimate and not permit any disclaimers to the contrary. A few commenters expressed understanding that some hospital costs are challenging to predict with certainty but asserted that in such cases, rather than a disclaimer, it would be useful to be offered a reasonable 'bundled' price for a procedure, along with prices for potential 'a la carte' items and services that could be included in the final bill.

A few commenters requested that CMS delay finalizing any additional criteria for the use of hospital price estimator tools. Commenters noted that both the Transparency in Coverage rule as well as the No Surprises Act have requirements for payers to establish price comparison tools.[598] Additionally, the No Surprises Act includes requirements for providers to communicate ''good faith estimates'' to uninsured (including self-pay) patients as well as communication of estimated charges to payers so that payers can, in turn, provide a ''good faith estimate'' to people using insurance. Commenters suggest that the estimates provided by hospital price estimator tools could be related to the ''good faith estimates'' that hospitals will be required to provide under the No Surprises Act. As such, commenters requested that CMS consider and ensure alignment of requirements across these initiatives.

Response: We appreciate commenter support for our Hospital Price Transparency final rule policies related to voluntary use of price estimator tools to satisfy the consumer-friendly display requirements at 45 CFR 180.60. We do not believe the clarification we provided in the proposed rule presents a change to the existing price estimator tool requirements that we previously finalized. However, we appreciate comments related to changes that we may consider in future rulemaking (such as expanding the policy to permit such tools to satisfy other requirements or rescinding the policy to permit hospitals to meet requirements for a consumer-friendly display via use of price estimator tools).

We appreciate commenter support for the clarification of the requirement that voluntary price estimator tools take into account patient insurance information when presenting out-of-pocket estimates. We agree that such tools are routinely used in hospital systems and can be used to provide meaningful and accurate estimates to consumers about their out-of-pocket obligations. We also noted in the Hospital Price Transparency final rule ''that price estimator tools pick up where our rule ends and take the additional steps that would otherwise be required by the consumer to determine their individualized out-of-pocket *by combining hospital standard charge information with the individual's benefit information directly from the insurer* [italics added for emphasis].'' (84 FR 65578).

Thus, the estimate from a price estimator tool, voluntarily used by the hospital in lieu of making public a consumer-friendly list of standard charges, must be tailored to individuals' circumstances and represent a real-time individualized out-of-pocket estimate of the amount they would have to pay the hospital that takes into account any applicable benefit information.

However, although we would expect a personalized out-of-pocket estimate to use hospital standard charges and to take insurer information directly into account, we did not specify the method by which a price estimator tool would do so. As suggested by commenters, we recognize that a population-based analysis of prior reimbursements for hospital services (particularly for complex procedures that have many possible combinations of items and services and corresponding payer-specific negotiated charges, or for procedures that have payer-specific negotiated charges for a service package based on complex contracting arrangements) could help inform the inputs (for example, items and services and total expected payer-specific negotiated charges) that are likely to be encountered by the individual. Additionally, we agree with commenters that there may be existing challenges for electronically accessing some payer information that is necessary to determine an accurate out-of-pocket cost estimate for all individuals seeking to use insurance, and that such challenges may require an individual to input data that comes directly from the payer. Further, we recognize that there may be an opportunity in the future to align requirements for a consumer-friendly display of standard charges with the requirements of the Transparency in Coverage regulations and the implementation of the No Surprises Act.

Accordingly, if a hospital chooses to offer a price estimator tool in lieu of displaying standard charges in a consumer-friendly manner, the hospital must ensure (among the other requirements at 45 CFR 180.60(a)(2)) that the tool allows healthcare consumers to, at the time they use the tool, obtain an estimate of the amount that the hospital anticipates the individual would be obligated to pay. This means that the estimated amount is personalized and represented as a single out-of-pocket dollar amount that takes into account the individual's insurance status. However, the Hospital Price Transparency final rule is not prescriptive regarding the method by which a hospital's price estimator tool estimates the individual's single out-of-pocket dollar amount. Specifically, we note that nothing in the rule prevents a hospital from developing an accurate and reliable cost estimate using prior claims information or from providing additional information that may be useful to the end-user, such as the range of out-of-pocket costs for the population to which the individual belongs. However, the estimate of ''the amount'' the individual would be obligated to pay must be displayed as a single dollar out-of-pocket amount within the tool. Similarly, the Hospital Price Transparency final rule is not prescriptive regarding the method by which the tool accesses the individual's insurance information ''directly from the insurer.'' We therefore agree with commenters that the tool could require the consumer to manually submit such information in order to generate the estimated out-of-pocket amount.

Finally, the Hospital Price Transparency final rule requires price estimator tools to allow consumers to obtain an estimate of the amount ''they will be obligated to pay'' the hospital for the shoppable service and we encouraged hospitals to take note of best practices for developing accurate and reliable cost estimates and seek to ensure the price estimator tools they offer are maximally consumer-friendly. Additionally, as noted by commenters, we encouraged, but did not require, that hospitals ''provide appropriate disclaimers in their price estimator tools, including acknowledging the limitation of the estimation and advising the user to consult, as applicable, with his or her health insurer to confirm individual payment responsibilities and remaining deductible balances.'' As such, we believe such disclaimers should serve to educate the public regarding the estimate and should not be used to avoid making every attempt to ensure the estimate is accurate. We agree that the 'absence of unusual or unforeseeable circumstances' are not the only reasons why a price estimate may change and we encourage hospitals to use the disclaimer as an opportunity to identify, explain, and document any limitations of the analysis, including but not

[598] *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf*

limited to any assumptions and exclusions that were made when developing the estimate.

2. Responses To Request for Comment

In the CY 2022 OPPS/ASC proposed rule (86 FR 42312 through 42321), we sought comment on a number of issues including: (1) Input for future consideration related to the price estimator tool policies, including identifying best practices, common features, and solutions to overcoming common technical barriers; (2) whether we should require specific plain language standards, and, if so, what those plain language standards should be; (3) potential ways that we could highlight exemplar hospital price transparency practices; and (4) recommendations for improving standardization of the machine-readable file. We received approximately 396 timely comments on this RFI. We appreciate the detailed input provided by commenters on these topics.

XIX. Additional Hospital Inpatient Quality Reporting (IQR) Program Policies

A. Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) and eCQM Reporting Requirements in the Hospital IQR Program—Request for Information

1. Hospital IQR Program Background

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, 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); and
- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45360 through 45426);

We note this is not an exhaustive list of all prior rulemaking for the Hospital IQR Program. We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations.

In the CY 2022 OPPS/ASC proposed rule (86 FR 42321), we sought input through a request for information (RFI) regarding the Safe Use of Opioids—Concurrent Prescribing electronic clinical quality measure (eCQM) (NQF #3316e) (hereinafter referred to as the ''Safe Use of Opioids eCQM'') as well as our previously finalized policy of requiring hospitals to report on the Safe Use of Opioids eCQM beginning with the CY 2022 reporting period/FY 2024 payment determination (84 FR 42503 through 42505). We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42459) where we adopted the Safe Use of Opioids eCQM into the Hospital IQR Program beginning with the CY 2021 reporting period/FY 2023 payment determination. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42503 through 42505) in which we finalized our policy requiring hospitals to report on the Safe Use of Opioids eCQM beginning in the CY 2022 reporting period. We also refer readers to the FY 2021 IPPS/LTCH PPS final rule in which we finalized reporting of the Safe Use of Opioids eCQM as one of the four required eCQMs beginning with the CY 2022 reporting period/FY 2024 payment determination (85 FR 58933 through 58939). Specifically, for the CY 2022 reporting period/FY 2024 payment determination, hospitals will be required to report three self-selected calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQM. For the CY 2023 reporting period/FY 2025 payment determination and subsequent years hospitals will be required to report four calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQM. The Safe Use of Opioids eCQM is scheduled to be submitted to the National Quality Forum (NQF) in 2022 for re-endorsement consideration as part of the measure maintenance process. The purpose of the RFI was to gather public input for potential measure updates as we prepare for NQF re-endorsement of the endorsed Safe Use of Opioids—Concurrent Prescribing eCQM and to potentially inform any future rulemaking regarding this measure. We provide more detail on both the Safe Use of Opioids eCQM and the eCQM reporting requirements below.

2. Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e)

a. Overview

The Safe Use of Opioids eCQM seeks to reduce preventable mortality and the costs of adverse events associated with opioid use by encouraging providers to identify patients who have concurrent prescriptions for opioids, or opioids and benzodiazepines, and discouraging providers from prescribing these drugs concurrently, unless medically necessary or appropriate. This measure is intended to support a patient-centric approach to help identify and monitor patients at risk, and ultimately reduce the risk of harm to patients across the continuum of care. Specifically, the measure encourages providers to identify patients on medication combinations that could lead to adverse drug events at discharge and motivates providers to consider whether reevaluation of the current medication regimen is warranted. This measure ultimately seeks to help combat the opioid crisis, which has been declared a public health emergency and is recognized as a priority focus area for measurement by CMS and HHS. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42459) where we adopted the Safe Use of Opioids eCQM into the Hospital IQR Program beginning with the CY 2021 reporting period/FY 2023 payment determination.

The Safe Use of Opioids eCQM assesses the proportion of inpatient hospitalizations for patients 18 years of age and older prescribed, or continued on, two or more opioids or an opioid and benzodiazepine concurrently at discharge. The numerator is comprised of patients whose discharge medications include two or more active opioids or an active opioid and benzodiazepine resulting in concurrent therapy at discharge from the hospital-based encounter (84 FR 42452). The denominator consists of patients who have inpatient hospitalizations (inpatient stay less than or equal to 120 days) that end during the measurement period, where the patient is 18 years of age and older at the start of the encounter, and is prescribed a new or continuing opioid or benzodiazepine at discharge (84 FR 42452). Patients who have cancer or are receiving palliative care would be excluded from the denominator (84 FR 42452).

A lower percentage for the measure indicates fewer concurrent prescriptions written. We emphasize that the Safe Use of Opioids eCQM is not expected to have a measure rate of zero (84 FR 42456). Clinician judgment, clinical

appropriateness, or both may indicate that concurrent prescribing of two unique opioids, or an opioid and a benzodiazepine is medically necessary. For example, patients who are on medication for opioid use disorder (OUD) would be included in the measure denominator if they continue that active prescription at discharge and would be counted in the numerator if they receive another prescription for an opioid or benzodiazepine (84 FR 42452). We also refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42459) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58932 through 58939) for more details on the Safe Use of Opioids eCQM.

b. Prior Stakeholder Feedback

We noted in the CY 2022 OPPS/ASC proposed rule (86 FR 42322) that we monitor and evaluate quality measures after they are adopted and implemented into the Hospital IQR Program measure set. We also engage with stakeholders through education and outreach opportunities, which include webinars and help desk questions submitted through the Office of the National Coordinator for Health Information Technology (ONC) Project Tracking System (JIRA) eCQM issue tracker for eCQM implementation and maintenance (84 FR 42454).

Since adopting the Safe Use of Opioids eCQM in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42459), stakeholders had expressed concern about potential unintended consequences associated with requiring reporting on the measure. Specifically, these stakeholders had noted their concern that requiring reporting on the Safe Use of Opioids eCQM could disincentivize clinicians from appropriately concurrently prescribing buprenorphine for the treatment of OUD. They believed that if hospitals are required to report on this measure, clinicians might alter their prescribing practices, making it more difficult for patients to access appropriate treatment for OUD, and ultimately leading to patient harm in a vulnerable population.

We noted that during measure development, clinicians from the expert panel convened by the measure developer on behalf of CMS considered single-condition exclusions such as OUD. After reviewing test results, they recommended continuing to include patients for whom concurrent prescribing is medically necessary, because they stated that those populations: (1) Have the highest risk of receiving concurrent prescriptions; (2) can experience a lag in adverse events; and (3) can experience adverse drug events if an overlap with benzodiazepines occurs (84 FR 42450 through 42451). As we previously noted in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42456), the Safe Use of Opioids eCQM is not expected to have a measure rate of zero; however, this is an important topic and a particular focus area of our monitoring efforts as the eCQM data start to be submitted and on which we sought comment, as further discussed below.

c. National Quality Forum Re-Endorsement

The Safe Use of Opioids eCQM is scheduled to be submitted to the NQF in 2022 for re-endorsement. In support of that effort, we noted that our measure development contractor plans to conduct additional testing, which will include substance use disorder treatment and sickle cell disease. Testing will include discussions with the technical expert panel to identify any potential updates to test as well as testing the rate of concurrent morphine/buprenorphine prescribing alongside opioids and benzodiazepines. Testing work will also include recruiting test sites, receiving test site data, reassessing validity, reliability, performance scores, exclusions, and performance gaps. This testing could be used to inform possible future measure updates or exclusions.

3. Current eCQM Reporting and Submission Requirements for the Hospital IQR Program

Beginning with the CY 2021 reporting period/FY 2023 payment determination, the Safe Use of Opioids eCQM was added as part of the eCQM measure set as one of the eCQMs that eligible hospitals can choose from to meet the eCQM reporting requirements for the Hospital IQR and Medicare Promoting Interoperability Programs (84 FR 42449 through 42459 and 84 FR 42598 through 42599, respectively). Beginning with the CY 2022 reporting period/FY 2024 payment determination, hospitals are required to report data for each required eCQM: (a) Three self-selected eCQMs from the set of available eCQMs for CY 2022, and (b) the Safe Use of Opioids eCQM (85 FR 58933 through 58939). We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58932 through 58939) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42501 through 42506) for more detailed discussions of the current eCQM reporting and submission requirements for the Hospital IQR Program.

4. Solicitation of Comments

In the RFI, we sought public input on the following:

- *Potential future measure updates of the Safe Use of Opioids eCQM.* We sought additional information or considerations to inform future measure updates to the Safe Use of Opioids eCQM.
- *Required Reporting and Submission Requirement for the Safe Use of Opioids eCQM.* Currently, hospitals are required to report: (a) Three self-selected eCQMs from the set of available eCQMs, and (b) the Safe Use of Opioid eCQM for the CY 2022 reporting period/FY 2024 and subsequent years. As we consider future reporting on the Safe Use of Opioids eCQM, we sought comments on the appropriateness of maintaining this previously finalized policy or allowing hospitals to self-select the Safe Use of Opioids eCQM from our finalized set of eCQMs.

We received comments on these topics.

Comment: Several commenters suggested that CMS should not mandate reporting of the Safe Use of Opioids eCQM, and instead retain the measure as an option to self-select to fulfill the eCQM requirement. Several commenters also requested that CMS delay mandatory reporting until NQF re-endorsement or until the concern about unintended consequences has been addressed.

Response: We thank the commenters for their inputs and interest in this measure. We believe that these comments are very valuable to both the continued development of the Safe Use of Opioids eCQM and also the Hospital IQR Program's reporting policies. We will continue to take these comments into account as we develop future regulatory proposals or other guidance for the Safe Use of Opioids eCQM.

Comment: Several commenters recommended refinements to the measure specifications for the Safe Use of Opioids eCQM. Several commenters urged us to consider incorporating more exclusions, such as for single-condition exclusions (opioid use disorder), appropriate concurrent prescribing, HIV, ESRD, opioid prescriptions from outside facilities, or long encounters (such as those 120 days or longer). Some commenters suggested revising the measure to report on the prevalence of addiction specialists and formal addiction medicine programs. Some commenters requested that the measure be revised to allow for appropriate concurrent prescribing and prevent unintended consequences. One commenter requested that the measure

specifications be clarified so that one prescription for differing dosage of a medication would not be interpreted as two prescriptions for purposes of the Safe Use of Opioids eCQM. One commenter requested that CMS focus on co-prescriptions of opioids and specific benzodiazepines because concurrent prescription of these medications carry a higher risk of accidental overdose and mortality.

Response: We thank the commenters for their suggestions and interest in refinements to this measure. We believe that these comments are very valuable in the continuing development of the Safe Use of Opioids eCQM and will inform the NQF re-endorsement process. We will continue to take these comments into account as we develop future regulatory proposals or other guidance for the Safe Use of Opioids eCQM.

Comment: One commenter encouraged CMS to retain the required reporting of the Safe Use of Opioids eCQM, but also suggested that CMS identify and require reporting of other eCQMs to remove hospital choice.

Response: We thank the commenter for their suggestions and will consider them for future rulemaking.

Comment: One commenter suggested that we share information from the years in which the Safe Use of Opioids eCQM was voluntarily submitted via hospital selection.

Response: We thank the commenters for their input and interest in this measure. We will take this suggestion into consideration.

XX. Additional Medicare Promoting Interoperability Program Policies

A. Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) and eCQM Reporting Requirements in the Medicare Promoting Interoperability Program—Request for Information

1. Medicare Promoting Interoperability Program Background

We refer readers to the following final rules for detailed discussions regarding the history of the Medicare Promoting Interoperability Program (previously known as part of the Medicare and Medicaid Electronic Health Record Incentive Programs):

- The Electronic Health Record Incentive Program Stage 1 final rule (75 FR 44314);
- The Electronic Health Record Incentive Program Stage 2 final rule (77 FR 53968);
- The Electronic Health Record Incentive Program Stage 3 final rule (80 FR 62762);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 25245 through 25247);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38487 through 38493);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41634 through 41677);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42591 through 42602);
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58966 through 58977); and
- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45460 through 45498).

We note this is not an exhaustive list of all prior rulemaking for the Medicare Promoting Interoperability Program. We also refer readers to 42 CFR part 495 for the Medicare Promoting Interoperability Program regulations.

In the CY 2022 OPPS/ASC proposed rule (86 FR 42323 through 42324), we sought input in a request for information (RFI), in alignment with the Hospital Inpatient Quality Reporting Program, regarding the Safe Use of Opioids—Concurrent Prescribing electronic clinical quality measure (eCQM) (NQF #3316e) (hereinafter referred to as the ''Safe Use of Opioids eCQM''), as well as our previously finalized policy of requiring hospitals to report on the Safe Use of Opioids eCQM beginning with the CY 2022 reporting period (84 FR 42598 through 42600 and 85 FR 58970 through 58975). We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42599) where we adopted the Safe Use of Opioids eCQM under the Medicare Promoting Interoperability Program beginning with the CY 2021 EHR reporting period, as we continued to align with the Hospital IQR Program. We also refer readers to the FY 2020 and FY 2021 IPPS/LTCH PPS final rules (84 FR 42597 through 42600 and 85 FR 58970 through 58975, respectively) where we finalized our policy requiring hospitals to report on the Safe Use of Opioids eCQM beginning with CY 2022 reporting period. The Safe Use of Opioids eCQM is scheduled to be submitted to the National Quality Forum (NQF) in 2022 for re-endorsement consideration as part of the measure maintenance process. The purpose of this RFI was to gather public input for potential measure updates as we prepare for NQF re-endorsement of the endorsed Safe Use of Opioids—Concurrent Prescribing eCQM and to potentially inform any future rulemaking regarding this measure. We provide more detail on both the Safe Use of Opioids eCQM and the eCQM reporting requirements in section [XX.A.3] of the CY 2022 OPPS/ASC proposed rule (section [XIX.A.3] of this final rule).

2. Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e)

a. Overview

The Safe Use of Opioids eCQM seeks to reduce preventable mortality, and the costs of adverse events associated with opioid use by encouraging providers to identify patients who have concurrent prescriptions for two or more opioids, or a combination of opioids and benzodiazepines, and discouraging providers from prescribing these drugs concurrently, unless medically necessary or appropriate. This measure is intended to support a patient-centric approach to help identify and monitor patients at risk, and ultimately reduce the risk of harm to patients across the continuum of care. Specifically, the measure encourages providers to identify patients receiving combinations of medications that could lead to adverse drug reactions at discharge, and motivates providers to consider whether a re-evaluation of the patient's current medication regimen is warranted. This measure ultimately seeks to help combat the opioid crisis, which has been declared a public health emergency and is recognized as a priority focus area for measurement by CMS and HHS.

The Safe Use of Opioids eCQM assesses the proportion of inpatient hospitalizations for patients 18 years of age and older who are prescribed, or continued on, two or more opioids or an opioid and benzodiazepine concurrently at discharge. The numerator is comprised of patients whose discharge medications include two or more active opioids, or an active opioid and benzodiazepine, resulting in concurrent therapy at discharge from the hospital-based encounter. The denominator consists of patients who have inpatient hospitalizations (inpatient stay less than or equal to 120 days) that end during the measurement period, where the patient is 18 years of age and older at the start of the encounter, and is prescribed a new or continuing opioid or benzodiazepine at discharge. Patients who have cancer or who are receiving palliative care would be excluded from the denominator (84 FR 42452).

A lower percentage for the measure indicates fewer concurrent prescriptions written. We emphasize that the Safe Use of Opioids eCQM is not expected to have a measure rate of zero (84 FR 42456). Clinician judgment, clinical appropriateness, or both, may indicate that concurrent prescribing of two unique opioids, or an opioid and a benzodiazepine is deemed medically necessary. Patients who are receiving medication for an opioid use disorder (OUD) would be included in the

measure denominator if they continue with their active prescription upon discharge, and would be counted in the numerator if they receive an additional prescription for an opioid or benzodiazepine (84 FR 42452). We also refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42599) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58932 through 58939) for more details on the Safe Use of Opioids eCQM.

b. Prior Stakeholder Feedback

We noted in the proposed rule (86 FR 42323 through 42324) that we monitor and evaluate quality measures after they are adopted and implemented under the Medicare Promoting Interoperability Program measure set. In collaboration with the Hospital IQR Program, we engage with stakeholders through education and outreach opportunities, which include webinars and help desk questions submitted through the Office of the National Coordinator for Health Information Technology (ONC) Project Tracking System (JIRA) eCQM issue tracker for eCQM implementation and maintenance (84 FR 42454).

Since adopting the Safe Use of Opioids eCQM in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42599), stakeholders have expressed concern about the potential for unintended consequences associated with requiring reporting on this measure. Specifically, stakeholders had noted that in requiring reporting on the Safe Use of Opioids eCQM, this could disincentivize clinicians from appropriately prescribing buprenorphine for the treatment of OUD. They believe that if hospitals are required to report on this measure, clinicians might alter their prescribing practices, making it more difficult for patients to access appropriate treatment for OUD, and ultimately, leading to potential patient harm in a vulnerable population.

We noted that during measure development, clinicians from the expert panel convened by the measure developer on behalf of CMS considered single-condition exclusions, such as OUD. After reviewing test results, they recommended continuing to include patients for whom concurrent prescribing is medically necessary, because they stated that those populations: (1) Have the highest risk of receiving concurrent prescriptions; (2) can experience a lag in adverse events; and (3) can experience adverse drug events if an overlap with benzodiazepines occurs (84 FR 42450 through 42451). As was explained by the Hospital IQR Program in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42456), the Safe Use of Opioids eCQM is not expected to have a measure rate of zero, however, this remains an important topic and a particular focus area of our monitoring efforts. For further discussion, we refer readers to section XX.A.4 of the CY 2022 OPPS/ASC proposed rule (section XIX.A.4 of this final rule with comment period).

c. National Quality Forum Re-Endorsement

The Safe Use of Opioids eCQM is scheduled to be submitted to the NQF in 2022 for re-endorsement. In support of that effort, we noted that our measure development contractor plans to conduct additional testing, which will include substance use disorder treatment and sickle cell disease. Testing will include discussions with the technical expert panel to inform potential updates to test, as well as testing the rate of concurrent morphine/buprenorphine prescribing alongside opioids and benzodiazepines. Testing work will also include recruiting test sites, receiving test site data, reassessing validity, reliability, performance scores, exclusions, and performance gaps. This testing could be used to inform possible future measure updates or exclusions.

3. Current eCQM Reporting and Submission Requirements for the Medicare Promoting Interoperability Program

The Medicare Promoting Interoperability Program previously finalized policy for the CY 2022 reporting period requiring that eligible hospitals and CAHs report on three self-selected calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs from the set of available eCQMs for CY 2022, and (b) the Safe Use of Opioids eCQM, for a total of four eCQMs (85 FR 58970 through 58975). We finalized the requirement that hospitals report on the Safe Use of Opioids eCQM in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42600), such that the Medicare Promoting Interoperability Program maintained alignment with proposals finalized under the Hospital IQR Program.

Beginning with the CY 2021 reporting period, the Safe Use of Opioids eCQM was added to the eCQM measure set as one of the eCQMs that eligible hospitals and CAHs can choose from to meet the eCQM reporting requirements for the Hospital Inpatient Quality Reporting Program and the Medicare Promoting Interoperability Program (84 FR 42449 through 42459 and 84 FR 42598 through 42599, respectively). We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58970 through 58975) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42600) for more detailed discussions of the current eCQM reporting and submission requirements for the Medicare Promoting Interoperability Program.

4. Solicitation of Comments

In the RFI, in alignment with a similar RFI pertaining to the Hospital IQR Program, we sought public comment on the following:

- *Potential future measure updates of the Safe Use of Opioids eCQM.* We sought additional information or considerations to inform future measure updates of the Safe Use of Opioids eCQM;
- *Required Reporting and Submission Requirement for the Safe Use of Opioids eCQM.* Currently eligible hospitals and CAHs are required to report (a) Three self-selected eCQMs from the set of available eCQMs, and (b) the Safe Use of Opioid eCQM for the CY 2022 reporting period and subsequent years. As we consider future reporting on the Safe Use of Opioids eCQM, we sought comment on the appropriateness of maintaining this previously finalized policy, or, allowing hospitals to self-select the Safe Use of Opioids eCQM from a finalized set of eCQMs (which includes the Safe Use of Opioids eCQM) for the CY 2022 EHR reporting period and subsequent years.

We received comments on these topics, and that feedback is summarized below.

Comment: Several commenters suggested that CMS not mandate the reporting of the Safe Use of Opioids eCQM, and instead retain the measure as optional, to fulfill the eCQM requirement. Several commenters also requested that CMS delay mandatory reporting until after NQF re-endorsement, or until the concern about unintended consequences has been addressed.

Response: We thank the commenters for their input and suggestions. We believe that these comments are valuable to both the continued development of the Safe Use of Opioids eCQM, and also the Medicare Promoting Interoperability Program's reporting policies. Alongside the Hospital IQR Program, we may take these comments under consideration as we develop future policy, or other guidance for the Safe Use of Opioids eCQM.

Comment: One commenter encouraged CMS to retain the required reporting of the Safe Use of Opioids eCQM, but also suggested that CMS

identify and require reporting of other eCQMs to remove, per hospital choice.

Response: We thank the commenter for their suggestions and may consider this for future rulemaking.

XXI. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and the final rules with comment period are published and available via the internet on the CMS website. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPS Addenda A, B, and C, by adding a column titled ''Copayment Capped at the Inpatient Deductible of $1,364.00'' where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). For CY 2022, we proposed to retain these columns, updated to reflect the amount of the 2022 inpatient deductible. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86266), we updated the format of the OPPS Addenda A, B, and C by adding a new column titled ''Drug Pass-Through Expiration during Calendar Year'' where we flagged through the use of an asterisk, each drug for which pass-through payment was expiring during the calendar year on a date other than December 31. For CY 2022, we did not receive any public comments and are, therefore, finalizing our proposal to retain these columns that are updated to reflect the drug codes for which pass-through payment is expiring in CY 2022.

To view the Addenda to the CY 2022 OPPS/ASC final rule with comment period pertaining to final CY 2022 payments under the OPPS, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; select ''CMS–1753–FC'' from the list of regulations. All OPPS Addenda to the CY 2022 OPPS/ASC final rule with comment period are contained in the zipped folder titled ''2022 NFRM OPPS Addenda'' in the related links section at the bottom of the page. To view the Addenda to the CY 2022 OPPS/ASC final rule with comment period pertaining to CY 2022 payments under the ASC payment system, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html*; select ''CMS–1753–FC'' from the list of regulations. The ASC Addenda to the CY 2022 OPPS/ASC final rule with comment period are contained in a zipped folder titled ''Addendum AA, BB, DD1, DD2, and EE.'' in the related links section at the bottom of the page.

XXII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), 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 title 44 of the U.S. Code, as added by section 2 of the Paperwork Reduction Act 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.

We solicited public comment on each of these issues for the following sections of this final rule with comment period that contain information collection requirements (ICRs):

B. ICRs for the Hospital OQR Program

1. Background

The Hospital Outpatient Quality Reporting (OQR) Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program. We refer readers to the CY 2011 through CY 2021 OPPS/ASC final rules (75 FR 72111 through 72114; 76 FR 74549 through 74554; 77 FR 68527 through 68532; 78 FR 75170 through 75172; 79 FR 67012 through 67015; 80 FR 70580 through 70582; 81 FR 79862 through 79863; 82 FR 59476 through 59479; 83 FR 59155 through 59156; 84 FR 61468 through 61469; and 85 FR 86266 through 86267, respectively) for detailed discussions of the previously finalized Hospital OQR Program ICRs. The ICRs associated with the Hospital OQR Program are currently approved under OMB control number 0938–1109, which expires on March 31, 2023. We continue to estimate a total of 3,300 hospitals will submit required measure data for the Hospital OQR Program, unless otherwise noted. While the exact number of hospitals required to submit data annually may vary, we use this estimate to be consistent with previous rules and for ease of calculation across reporting periods.

In the CY 2018 OPPS/ASC final rule (82 FR 52617), we finalized a proposal to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the Hospital OQR Program. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the Hospital OQR Program. The latest data from the BLS' May 2020 Occupational Employment and Wages data reflects a median hourly wage of $21.20 per hour for a Medical Records and Health Information Technician professional.[599] We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 52617). This is necessarily a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($21.20 × 2 = $42.40) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

2. Summary

In section XV.B.4. of this final rule with comment period, we are finalizing our proposals to: (1) Adopt the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure (OP–38), beginning with the CY 2022 reporting period; (2) adopt the Breast Cancer Screening Recall Rates measure (OP–39), beginning with the CY 2022 reporting period; (3) adopt the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM (OP–40), beginning as a voluntary measure with

[599] *https://www.bls.gov/oes/current/oes292098.htm* (Accessed April 13, 2021). The hourly rate of $42.40 includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

the CY 2023 reporting period, and then as a mandatory measure beginning with the CY 2024 reporting period; (4) require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey measures (OP–37 a-e), with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination; (5) remove the Fibrinolytic Therapy Received Within 30 Minutes measure (OP–2), effective with the CY 2023 reporting period; (6) remove the Median Time to Transfer to Another Facility for Acute Coronary Intervention measure (OP–3), effective with the CY 2023 reporting period; (7) remove the option for hospitals to send medical records to the CMS Data Abstraction Center (CDAC) via paper and removable media and require electronic submission for validation; (8) reduce the number of days hospitals have to submit medical records to the CDAC from 45 days to 30 days for validation; (9) enhance the targeting criteria used for hospital selection for validation by adopting criteria currently used in inpatient data validation by adding the following criteria: (a) Having a lower bound confidence interval score of 75 percent or less; and (b) having not been selected in the previous 3 years; (10) expand our Extraordinary Circumstances Exception (ECE) policy to apply to electronic clinical quality measures (eCQMs), to further align with the Hospital IQR Program; (11) require use of technology updated consistent with 2015 Edition Cures Update criteria beginning with the CY 2023 reporting period/CY 2025 payment determination; and (12) provide a review and corrections period for eCQM data submitted to the Hospital OQR Program. We are also finalizing our proposal with modification to require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure (OP–31) beginning with the CY 2025 reporting period/CY 2027 payment determination instead of the CY 2023 reporting period/CY 2025 payment determination.

3. Estimated Burden of Hospital OQR Program Requirements for the CY 2024 Payment Determination and Subsequent Years

a. Information Collection Burden Estimate for the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure (OP–38)

In section XV.B.4 of this final rule with comment period, we are finalizing our proposal to adopt the COVID–19 Vaccination Coverage Among HCP measure (OP–38), beginning with the CY 2022 reporting period/CY 2024 payment determination. Hospitals will submit data through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based surveillance system maintained and provided free by the CDC. Currently, the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA (OMB control number 0920–1317, which expires on January 31, 2024) because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[600] As such, the finalized adoption of this measure will not impose any additional information collection under the Paperwork Reduction Act for hospitals for the duration of the public health emergency (PHE), but will impose information collection burden for any reporting of this measure taking place after conclusion of the PHE. Although the burden associated with the COVID–19 Vaccination Coverage Among HCP measure (OP–38) is not accounted for under the CDC PRA 0920–1317 or 0920–0666 (which expires on December 31, 2023) due to the NCVIA waiver, the cost and burden information is included in the Regulatory Impact Analysis section. We will work with CDC to ensure that this burden is accounted for in an updated PRA under OMB control number 0920–1317.

b. Information Collection Burden Estimate for the Breast Cancer Screening Recall Rates Measure (OP–39)

In section XV.B.4.b of this final rule with comment period, we are finalizing our proposal to adopt the Breast Cancer Screening Recall Rates measure (OP–39), beginning with the CY 2023 payment determination using a data collection period of July 1, 2020, to June 30, 2021; for subsequent years, we will use data collection periods from July 1 through June 30 for the 3 years prior to the applicable payment calendar year (for example, for the CY 2024 payment determination, we will use data from July 1, 2021, through June 30, 2022). Because the measure is calculated using claims data that are already submitted to the Medicare program for payment purposes, we do not anticipate that adopting this measure will result in any increase in information collection burden.

c. Information Collection Burden Estimate for the ST-Segment Elevation Myocardial Infarction (STEMI) Measure (OP–40)

In section XV.B.4.c. of this final rule with comment period, we are finalizing our proposal to adopt the STEMI eCQM (OP–40), with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination. For the CY 2023 voluntary reporting period, hospitals will be able to voluntarily report the measure for one or more quarters during the year. For subsequent years, we are finalizing our proposal to gradually increase the number of quarters of data hospitals will be required to report on the measure starting with one self-selected quarter for the CY 2024 reporting period/CY 2026 payment determination, two self-selected quarters for the CY 2025 reporting period/CY 2027 payment determination, three self-selected quarters for the CY 2026 reporting period/CY 2028 payment determination, and four quarters for the CY 2027 reporting period/CY 2029 payment determination and for subsequent years.

For the voluntary reporting period in CY 2023, we estimate 20 percent of hospitals will voluntarily report at least one quarter of data for the measure with 100 percent of hospitals reporting the measure as required in subsequent years. Based on experience with reporting of eCQMs on the Hospital IQR program, we are aligning our estimate of the time required for a Medical Records and Health Information Technician professional to submit the data required for the measure to be 10 minutes per quarter for each hospital. For the CY 2023 voluntary reporting period, we estimate an annual burden for all participating hospitals of 110 hours (3,300 hospitals × 20 percent × .1667 hours × 1 quarter) at a cost of $4,664 (110 hours × $42.40). For the CY 2024 reporting period/CY 2026 payment determination, we estimate the annual burden for all participating hospitals to be 550 hours (3,300 hospitals × .1667 hours × 1 quarters) at a cost of $23,320 (550 hours × $42.40). For the CY 2025 reporting period/CY 2027 payment determination, we estimate the annual burden for all participating hospitals to be 1,100 hours (3,300 hospitals × .1667 hours × 2 quarters) at a cost of $46,640 (1,100 hours × $42.40). For the CY 2026 reporting period/CY 2028 payment determination, we estimate the annual

[600] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa-2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa-1.

burden for all participating hospitals to be 1,650 hours (3,300 hospitals × .1667 hours × 3 quarters) at a cost of $69,960 (1,650 hours × $42.40). For the CY 2027 reporting period/CY 2029 payment determination and subsequent years, we estimate the annual burden for all participating hospitals to be 2,200 hours (3,300 hospitals × .1667 hours × 4 quarters) at a cost of $93,280 (2,200 hours × $42.40).

The information collection requirement and the associated burden will be submitted as part of a revision of the information collection request currently approved under OMB control number 0938–1109, which expires on March 31, 2023.

d. Information Collection Burden Estimate for OP–31: Cataracts—Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure

As discussed in section XV.B.5.b. of this final rule with comment period, we are finalizing our proposal with modification to require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure (OP–31), beginning with the CY 2025 reporting period/CY 2027 payment determination instead of the proposed CY 2023 reporting period/CY 2025 payment determination. We previously finalized voluntary reporting of this measure in the CY 2015 OPPS/ASC final rule (79 FR 66947 through 66948) and estimated that 20 percent of hospitals would elect to report it annually (79 FR 67014). We continue to estimate it will require hospitals 10 minutes once annually to report this measure using a CMS web-based tool. As a result of this policy, we estimate a total annual burden estimate for all participating hospitals of 550 hours (3,300 hospitals × 0.1667 hours) at a cost of $23,320 (550 hours × $42.40). In addition to reporting the measure, we also require hospitals to perform chart abstraction and estimate that each hospital would spend 25 minutes (0.417 hours) per case to perform this activity. The currently approved burden estimate assumes 384 cases requiring chart abstraction per measure. We are updating this assumption to 242 cases per measure based on data from the CY 2019 reporting period. Updating this assumption results in an annual burden of 101 hours (0.417 hours × 242 cases) at a cost of $4,282 (101 hours × $42.40/hour) per hospital and a total annual burden of 333,300 hours (3,300 hospitals × 101 hours) at a cost of $14,131,920 (333,300 hours × $42.40/hour) for all participating hospitals. In aggregate, we estimate a total annual burden of 333,850 hours (550 hours + 333,300 hours) at a cost of $14,155,240 ($23,320 + $14,131,920) for all hospitals. This is an increase of 267,080 hours and $11,324,192 per year from the currently approved estimate due to the additional 80 percent of hospitals that will be required to report this measure.

The information collection requirement and the associated burden will be submitted as part of a revision of the information collection request currently approved under OMB control number 0938–1109, which expires on March 31, 2023.

e. Information Collection Burden Estimate for the Requirement of OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures and Add Administration Methods

The information collection requirements associated with the five OAS CAHPS survey-based measures (OP–37a, OP–37b, OP–37c, OP–37d, and OP–37e) are currently approved under OMB control number 0938–1240 which expires December 31, 2021. In section XV.B.5.a. of this final rule with comment period, we are finalizing our proposal to require data collection for five OAS CAHPS survey-based measures with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination and subsequent years: (1) OAS CAHPS—About Facilities and Staff (OP–37a); (2) OAS CAHPS—Communication About Procedure (OP–37b); (3) OAS CAHPS—Preparation for Discharge and Recovery (OP–37c); (4) OAS CAHPS—Overall Rating of Facility (OP–37d); and (5) OAS CAHPS—Recommendation of Facility (OP–37e). Finalizing this proposal will neither require additional questions to be added to the survey nor any other changes which will affect the time required for respondents to complete the survey. Therefore, we are not making any changes to the currently approved burden estimate of 8 minutes per respondent.

In addition, in section XV.D.4.b of this final rule with comment period, we are finalizing our proposal to incorporate two additional administration methods for the OAS CAHPS Survey: (1) Mixed mode web with mail follow-up of non-respondents, and (2) mixed mode web with telephone follow-up of non-respondents. This will allow a total of five methods of survey administration for reporting beginning with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting for the CY 2025 reporting period/CY 2027 payment determination. We currently assume that completion of the OAS CAHPS survey requires approximately 8 minutes per respondent using one of the three current administration methods (mail-only, telephone-only, and mixed-mode (mail with telephone follow-up of non-respondents)). The two additional administration methods will be utilized to increase the response rate of patients to achieve the same required number of 300 patients surveyed per practice; therefore, we are not changing the number of respondents. We also believe that the two administration methods will require approximately the same time to conduct; therefore, we are not changing the currently approved estimate.

f. Information Collection Burden Change for the Removal of Measures OP–2: The Fibrinolytic Therapy Received Within 30 Minutes and OP–3: Median Time To Transfer to Another Facility for Acute Coronary Intervention

In section XV.B.3.c. of this final rule with comment period, we are finalizing our proposal to remove the Fibrinolytic Therapy Received Within 30 Minutes (OP–2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP–3) measures effective with the CY 2023 reporting period. The currently approved burden estimate under OMB control number 0938–1109 (which expires on March 31, 2023) for all participating hospitals is 151,800 hours at a cost of $6,436,320 (151,800 hours × $42.40) for each measure per year. We estimate a total burden decrease of 303,600 hours (151,800 hours × 2 measures) at a cost of $12,872,640 (303,600 hours × $42.40). The information collection under OMB Control number 0938–1109 will be revised and submitted to OMB for approval.

g. Information Collection Burden Estimate for the Removal of the Option for Hospitals to Send Medical Records to the Validation Contractor via Paper and Removable Media and Require Electronic Submission

In section XV. D.9.b. of this final rule with comment period, we are finalizing our proposal to remove the option for hospitals to send medical records to the validation contractor via paper and removable media and are requiring electronic submission. As noted in the CY 2015 OPPS/ASC final rule (79 FR 67015), we have been reimbursing hospitals directly for expenses

associated with submission of medical records for data validation. Specifically, we reimbursed hospitals at 12 cents per photocopied page; for hospitals providing medical records digitally via a rewritable disc, such as encrypted Compact Disc—Read Only Memory, Digital Video Discs, or flash drives, we reimbursed hospitals at a rate of 40 cents per disc, along with $3.00 per record; and for hospitals providing medical records as electronic files submitted via secure file transmission, we reimburse hospitals at $3.00 per record. Because we directly reimburse, we do not anticipate any net change in information collection burden associated with our finalized proposal to require electronic file submissions of medical records via secure file transmission for hospitals selected for chart-abstracted measures validation. Hospitals will continue to be reimbursed at $3.00 per record for electronic files submitted via secure file transmission.

h. Information Collection Burden Estimate for the Reduction in the Number of Days Hospitals Have To Submit Medical Records to the CDAC From 45 Days to 30 Days

In section XV.D.9.b. of this final rule with comment period, we are finalizing our proposal to reduce the number of days hospitals would have to submit medical records to the CDAC from 45 days to 30 days. We expect that this will not yield a change in burden as it does not affect the amount of data required for hospitals to submit. We discuss administrative burdens regarding this change in section XXV.C.4.b. of this final rule with comment period. The existing information collection requirement and the associated burden are currently approved under OMB control number 0938–1109, which expires on March 31, 2023.

i. Information Collection Burden Estimate for the Addition of Targeting Criteria Used for Hospital Selection by Adopting Criteria Currently Used in Inpatient Data Validation

In section XV.D.9.d.(2). of this final rule with comment period, we are finalizing our proposal to add to the targeting criteria used for hospital selection for validation by adopting criteria currently used in inpatient data validation by adding the following criteria: (a) Having a lower bound confidence interval score of 75 percent or less; and (b) having not been selected in the previous 3 years. We expect that this will not yield a change in burden as it does not affect the total number of hospitals selected for data validation nor the data submission requirements for the hospitals selected. The existing information collection requirement and the associated burden are currently approved under OMB control number 0938–1109, which expires on March 31, 2023.

j. Information Collection Burden Estimate for Expanding our Existing ECE Policy To Apply to Electronic Clinical Quality Measures (eCQMs).

In section XV.D.10.b. of this final rule with comment period, we are finalizing our proposal to expand our existing ECE policy to apply to eCQMs, to further align with the Hospital IQR Program. The burden associated with submission of the ECE request form is included under OMB control number 0938–1022 which expires on December 31, 2022. As noted in 0938–1022, the total estimated burden for all hospitals participating in the CMS Quality Reporting Programs for completing forms including the ECE request form is 1,100 hours. In CY 2017, 166 ECE requests were submitted by hospitals for an exception from reporting requirements in the Hospital IQR Program. Based on the estimate of 15 minutes per record to submit the ECE request form, the total burden calculation for the submission of 166 ECE requests was 2,490 minutes (or 41.5 hours) across 3,300 hospitals. We are unable to forecast the number of additional ECE requests which may be submitted as a result of this change; however, we continue to estimate that each submission will continue to require approximately 15 minutes to complete. Using this estimate of 15 minutes per submission, our estimate of 1,100 hours would be adequate to account for a maximum of 4,400 submissions (1,100 hours ÷ 0.25 hours/submission), or 4,234 more than what was received in CY 2017. Therefore, we believe the estimate of 1,100 hours across all hospitals is conservative enough to account for any increase in burden that may be associated with this finalized change in ECE policy.

k. Information Collection Burden Estimate for the Required Use of 2015 Edition Cures Update Certified Technology

In section XV.D.6.c.(1). of this final rule with comment period, we are finalizing our proposal that hospitals use certified technology updated consistent with the 2015 Edition Cures Update beginning with the CY 2023 reporting period/CY 2025 payment determination and subsequent years, which includes both the voluntary period and required submissions of eCQMs. We do not expect that this would affect our information collection burden estimates currently approved under OMB control number 0938–1109 (which expires on March 31, 2023) because this policy does not require hospitals to submit additional data to CMS. With respect to any costs unrelated to data submission, we refer readers to section XXV.C.4.b. of this final rule with comment period.

l. Information Collection Burden Estimate for the Review and Corrections Period for eCQM Data Submitted to the Hospital OQR Program

In section XV.D.8 of this final rule with comment period, we are finalizing our proposal that hospitals would have a review and corrections period for eCQM data submitted to the Hospital OQR Program. Early testing and the use of pre-submission testing tools to reduce errors and inaccurate data submissions in eCQM reporting is encouraged but not required; therefore, we are unable to estimate the number of hospitals that may elect to submit test data files. We account for the burden of submission of production data files in section XXIII.B.3.C. of this final rule with comment period. Similar to our previously finalized burden assumptions regarding a review and corrections period for chart-abstracted measures (79 FR 66964 and 67014) and web-based measures (85 FR 86184 and 86267), this finalized period does not require hospitals to submit additional data and therefore we do not believe it will increase burden for these hospitals.

4. Summary of Information Collection Burden Estimates for the Hospital OQR Program

In summary, under OMB control number 0938–1109 which expires on March 31, 2023, we estimate that the updated assumptions and policies promulgated in this final rule with comment period will result in a decrease of 73,344 hours annually for 3,300 OPPS hospitals across a 5-year period from the CY 2022 reporting period/CY 2024 payment determination through the CY 2027 reporting period/CY 2029 payment determination. The total cost decrease related to this information collection is approximately −$3,109,786 (−73,344 hours × $42.40/hour) (which also reflects use of an updated hourly wage rate as previously discussed). Tables 77, 78, 79, 80, and 81 summarize the total burden changes for each respective CY payment determination compared to our currently approved information collection burden estimates (the table for the CY 2029 payment determination

reflects the cumulative burden changes). We note that for the STEMI eCQM (OP–40), the tables do not reflect the maximum burden for the CY 2025 payment determination, because we estimate only 20 percent of hospitals will voluntarily report the measure during the CY 2023 reporting period. While it is possible that more than 20 percent of hospitals may voluntarilyreport the measure during the CY 2023 reporting period, this percentage is consistent with our experience implementing eCQM measures with voluntary reporting periods under the Hospital IQR Program. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1109.[601]

BILLING CODE 4120–01–P

TABLE 77: Summary of Hospital OQR Program Information Collection Burden Change for the CY 2023 Reporting Period/CY 2025 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2025 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add OP-40 Measure	10	4	660	1	0.67	440	N/A	+440
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800
	Total Change in Information Collection Burden Hours: -303,160							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-303,160) = **-$12,853,984**							

TABLE 78: Summary of Hospital OQR Program Information Collection Burden Change for the CY 2024 Reporting Period/CY 2026 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2026 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add OP-40 Measure	10	1	3,300	1	0.167	550	N/A	+550
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800

[601] CY 2020 Final Rule Hospital OQR Program ''Supporting Statement—A''. Available at: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201911-0938-015.*

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2026 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
	Total Change in Information Collection Burden Hours: -303,050							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-303,050) = **-$12,849,320**							

TABLE 79: Summary of Hospital OQR Program Information Collection Burden Change for the CY 2025 Reporting Period/CY 2027 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Payment Determinations							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add OP-40 Measure	10	2	3,300	1	0.33	1,100	N/A	+1,100
Require OP-31 Measure	10	1	3,300	1	0.167	550	110	+440
Require Chart Abstraction for OP-31 measure	25	1	3,300	242	101	333,300	105,684	+227,616
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800
	Total Change in Information Collection Burden Hours: -74,444							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-74,444) = **-$3,156,426**							

TABLE 80: Summary of Hospital OQR Program Information Collection Burden Change for the CY 2026 Reporting Period/CY 2028 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2028 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add OP-40 Measure	10	3	3,300	1	0.50	1,650	N/A	+1,650
Require OP-31 Measure	10	1	3,300	1	0.167	550	110	+440
Require Chart Abstraction for OP-31 measure	25	1	3,300	242	101	333,300	105,684	+227,616
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800
	Total Change in Information Collection Burden Hours: -73,894							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-73,894) = **-$3,133,106**							

TABLE 81: Summary of Hospital OQR Program Information Collection Burden Change for the CY 2027 Reporting Period/CY 2029 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2029 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add OP-40 Measure	10	4	3,300	1	0.67	2,200	N/A	+2,200
Require OP-31 Measure	10	1	3,300	1	0.167	550	110	+440

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2029 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Require Chart Abstraction for OP-31 measure	25	1	3,300	242	101	333,300	105,684	+227,616
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800
	Total Change in Information Collection Burden Hours: -73,344							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-73,344) = **-$3,109,786**							

BILLING CODE 4120–01–C

C. ICRs for the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), and the CY 2013, CY 2014, CY 2015, CY 2016, CY 2017, CY 2018, CY 2019, CY 2020, and CY 2021 OPPS/ASC final rules (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; 80 FR 70582 through 70584; 81 FR 79863 through 79865; 82 FR 59479 through 59481; 83 FR 59156 through 59157; 84 FR 61469; and 85 FR 86267, respectively) for detailed discussions of the Ambulatory Surgical Center Quality Reporting (ASCQR) Program ICRs we have previously finalized. The ICRs associated with the ASCQR Program for the CY 2014 through CY 2023 payment determinations are currently approved under OMB control number 0938–1270, which expires on December 31, 2022.

In the CY 2018 OPPS/ASC final rule (82 FR 52619 through 52620), we finalized a proposal to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the BLS, to calculate our burden estimates for the ASCQR Program. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the ASCQR Program. The latest data from the BLS' May 2020 Occupational Employment and Wages data reflects a median hourly wage of $21.20 per hour for a Medical Records and Health Information Technician professional.[602] We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 52619 through 52620). This by necessity is a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($21.20 × 2 = $42.40) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

Based on an analysis of the CY 2020 payment determination data, we found that of the 6,651 ASCs that met eligibility requirements for the ASCQR Program, 3,494 were required to participate in the Program and did so. In addition, 689 ASCs that were not required to participate, did so, for a total of 4,183 participating facilities. As noted in section XXV.C.5.a. of the Regulatory Impact Analysis, for the CY 2021 payment determination, all 6,811 ASCs that met eligibility requirements for the ASCQR Program received the annual payment update due to data submission requirements being excepted under the ASCQR Program's ECE policy in consideration of the COVID–19 PHE; 3,957 of these ASCs would have been required to participate without the PHE exception. Therefore, we estimate that 3,957 plus 689, or 4,646, ASCs will submit data for the ASCQR Program for the CY 2022 payment determination unless otherwise noted.

2. Summary

In section XVI. B.3.a. and XVI. B.4. of this final rule with comment period, we are finalizing our proposals to: (1) Adopt the COVID–19 Vaccination Coverage Among HCP measure, beginning with the CY 2022 reporting period/CY 2024 payment determination (ASC–20); (2) require four patient safety outcome measures beginning with the CY 2023 reporting period/CY 2025 payment determination: (a) Patient Burn (ASC–1); (b) Patient Fall (ASC–2); (c) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC–3); and (d) All-Cause Hospital Transfer/Admission (ASC–4); and (3) add two additional data collection survey modes of OAS CAHPS measures collection to the existing three modes of collection and provide survey administration requirements. We are finalizing with modification our proposals to: (1) Require the Cataracts: Improvement in Patient's Visual

[602] *https://www.bls.gov/oes/current/oes292098.htm* (Accessed April 13, 2021). The hourly rate of $42.40 includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

Function within 90 days Following Cataract Surgery (ASC–11) measure beginning with the CY 2025 reporting period/CY 2027 payment determination instead of the CY 2023 reporting period/CY 2025 payment determination; and (2) require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey measures (ASC–15 a–e) with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2025 reporting period/CY 2027 payment determination instead of the CY 2024 reporting period/CY 2026 payment determination.

3. Estimated Burden of ASCQR Program Proposals for the CY 2024 Payment Determination and Subsequent Years

a. Information Collection Burden Estimate for the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure (ASC–20)

In section XVI.B.3.a. of this final rule with comment period, we are finalizing our proposal to adopt the COVID–19 Vaccination Coverage Among HCP measure (ASC–20), beginning with the CY 2022 reporting period/CY 2024 payment determination. ASCs will submit data through the NHSN, a secure, internet-based surveillance system maintained and provided free by the CDC. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA (OMB control number 0920–1317, which expires on January 31, 2024) because the agency has been granted a waiver under section 321 of the NCVIA.[603] As such, the burden associated with the COVID–19 Vaccination Coverage Among HCP measure (ASC–20) has not been accounted for under the CDC PRA 0920–1317 or 0920–0666 (which expires on December 31, 2023) due to the NCVIA waiver, however the cost and burden information is included in the Regulatory Impact Analysis section. We will work with CDC to ensure that the burden is accounted for in an updated PRA under OMB control number 0920–1317.

[603] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa-2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

b. Information Collection Burden Estimate for the Requirement of Four Patient Safety Outcome Measures: Patient Burn (ASC–1); Patient Fall (ASC–2); Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC–3); and All-Cause Hospital Transfer/Admission (ASC–4)

In section XVI.B.4.a of this final rule with comment period, we are finalizing our proposal to resume and require four patient safety outcome measures beginning with the CY 2023 reporting period/CY 2025 payment determination: (1) Patient Burn (ASC–1); (2) Patient Fall (ASC–2); (3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC–3); and (4) All-Cause Hospital Transfer/Admission (ASC–4). Measure data for these measures will be submitted via the CMS Hospital Quality Reporting (HQR) system secure portal (also known as the CMS QualityNet Secure Portal). Consistent with prior years (78 FR 75171 through 75172), we estimate that each participating facility will spend 10 minutes per measure per year to collect and submit the data via a CMS web-based tool (OMB control number 0938—1270, which expires on December 31, 2022). As a result of finalizing this requirement, we estimate a resulting total annual burden estimate for all ASCs of 3,098 hours (0.1667 hours/measure × 4 measures × 4,646 ASCs) at a cost of $131,355 (3,098 hours × $42.40). The information collection under OMB Control number 0938—1270 will be revised and submitted to OMB for approval.

c. Information Collection Burden Estimate for the ASC–11, Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure

As discussed in section XVI.B.4.b. of this final rule with comment period, we are finalizing with modification our proposal to require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC–11) measure beginning with the CY 2025 reporting period/CY 2027 payment determination instead of the CY 2023 reporting period/CY 2025 payment determination. We previously finalized voluntary reporting of this measure in the CY 2015 OPPS/ASC final rule (79 FR 66985) and estimated that 20 percent of ASCs would elect to report it annually (79 FR 67016). We continue to estimate it will require ASCs 10 minutes once annually to report this measure. As a result of this policy, we estimate a total annual burden estimate for all ASCs to report the measure of 774 hours (4,646 ASCs × 0.1667 hours) at a cost of $32,818 (774 hours × $42.40). In addition to reporting the measure, we also require ASCs to perform chart abstraction for a minimum required yearly sample size of 63 cases. We estimate that each ASC would spend 15 minutes per case to perform this activity. As a result of this policy, we estimate an annual burden of 16 hours (0.25 hours × 63 measures) at a cost of $678 (16 hours × $42.40) per ASC and a total annual burden of 74,336 hours (4,646 ASCs × 16 hours) at a cost of $3,151,846 (74,336 hours × $42.40). In aggregate, we estimate a total annual burden of 75,110 hours (774 + 74,336) at a cost of $3,184,664 (75,110 hours × $42.40) for all ASCs. Considering the increase in the number of ASCs submitting data, there is an increase of 60,088 hours (75,110 hours × 80 percent) and $2,547,731 ($3,184,664 × 80 percent) per year from the currently approved estimate (OMB control number 0938–1270, which expires on December 31, 2022) due to the additional 80 percent of ASCs that would be reporting this measure. The information collection under OMB Control number 0938–1270 will be revised and submitted to OMB for approval.

d. Information Collection Burden Estimate for the Requirement of ASC–15 a–e: The Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures and Incorporation of Additional Administration Methods

The information collection requirements associated with the five OAS CAHPS Survey-based measures (proposed ASC–15a, ASC–15b, ASC–15c, ASC–15d, and ASC–15e) are currently approved under OMB control number 0938–1240 which expires December 31, 2021.In section XVI.B.4.c. of this final rule with comment period, we are finalizing our proposal with modification to require five OAS CAHPS Survey-based measures with voluntary reporting beginning with the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting beginning with CY 2025 reporting period/CY 2027 payment determination and subsequent years: (1) ASC–15a: OAS CAHPS—About Facilities and Staff; (2) ASC–15b: OAS CAHPS—Communication About Procedure; (3) ASC–15c: OAS CAHPS—Preparation for Discharge and Recovery; (4) ASC–15d: OAS CAHPS—Overall Rating of Facility; and (5) ASC–15e: OAS CAHPS—Recommendation of Facility. Finalizing this change will

neither require additional questions to be added to the survey nor any other changes which will affect the time required for respondents to complete the survey. Therefore, we are not making any changes to the currently approved burden estimate of 8 minutes per respondent.

In addition, in section XVI.D.1.d.(2). of this final rule with comment period, we finalized our proposal to incorporate two additional administration methods for the OAS CAHPS Survey: (1) Mixed mode web with mail follow-up of non-respondents, and (2) mixed mode web with telephone follow-up of non-respondents. The addition of these two survey administration methods will provide a total of five methods of survey administration for reporting beginning with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting for the CY 2025 reporting period/CY 2027 payment determination. We currently assume that completion of the OAS CAHPS survey requires approximately 8 minutes per respondent using one of the three current administration methods (mail-only, telephone-only, and mixed-mode (mail with telephone follow-up of nonrespondents)). We believe that the two administration methods will require approximately the same time to conduct, therefore, we are not changing the currently approved estimate. In addition, the two administration methods will be utilized to increase the response rate of patients to achieve the same required number of 200 patients surveyed per practice, therefore we are not changing the number of respondents.

e. Summary of Information Collection Burden Estimates for the ASCQR Program

In summary, under OMB control number 0938–1270 which expires on December 31, 2022, we estimate that the policies promulgated in this final rule with comment period will result in an increase of 67,085 hours annually for 4,646 ASCs across a 4-year period from the CY 2023 reporting period/CY 2025 payment determination through the CY 2026 reporting period/CY 2028 payment determination. The total cost increase related to this information collection is approximately $2,844,404 (67,085 hours × $42.40). Tables 82 and 83 summarize the total burden changes for each respective CY payment determination compared to our currently approved information collection burden estimates. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1270.[604]

BILLING CODE 4120–01–P

TABLE 82: Summary of ASCQR Program Information Collection Burden Change for the CY 2023 Reporting Period/CY 2025 Payment Determination through CY 2024 Reporting Period/CY 2026 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2025 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Require ASC 1-4 measures	10	1	4,646	4	0.67	3,098	N/A	+3,098
	Total Change in Information Collection Burden Hours: +3,098							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (+3,098) = **+$131,355**							

[604] CY 2021 Final Rule ASCQR Program ''Supporting Statement-A''. Available at: *https://www.reginfo.gov/public/do/DownloadDocument?objectID=108544300.*

TABLE 83: Summary of ASCQR Program Information Collection Burden Change for the CY 2025 Reporting Period/CY 2027 Payment Determination through CY 2026 Reporting Period/CY 2028 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2027 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Require ASC 1-4 measures	10	1	4,646	4	0.67	3,098	N/A	+3,098
Require ASC-11 Measure	10	1	4,646	1	.1667	774	116.7	+657
Require Chart Abstraction for ASC-11 Measure	15	1	4,646	63	16	74,336	11,006	+63,330
	Total Change in Information Collection Burden Hours: +67,085							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (+67,085) = **+$2,844,404**							

BILLING CODE 4120–01–C

All comments on the CY 2022 OPPS/ASC proposed rule were received on or by September 17, 2021.

XXIII. 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 considered all comments we received by the date and time specified in the **DATES** section of this preamble and responded to the comments in the preamble of this final rule with comment period.

XXIV. Economic Analyses

A. Statement of Need

This final rule with comment period is necessary to make updates to the Medicare hospital OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2022. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are revising the APC relative payment weights using claims data for services furnished on and after January 1, 2019, through and including December 31, 2019, and processed through June 30, 2020, and prior cost report information, consistent with our final policy of using data prior to the start of the PHE.

This final rule with comment period also is necessary to make updates to the ASC payment rates for CY 2022, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in ASCs in CY 2022. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC, not less frequently than every 2 years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to update the ASC payment system rates using the hospital market basket update instead of the CPI–U for CY 2019 through 2023. We believe that this policy will help stabilize the differential between OPPS payments and ASC payments, given that the CPI–U has been generally lower than the hospital market basket, and encourage the migration of services to lower cost settings as clinically appropriate.

B. Overall Impact of Provisions of This Final Rule With Comment Period

We have examined the impacts of this final rule with comment period, 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), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security 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 (5 U.S.C. 804(2)). This section of this final rule with comment period contains the impact and other economic analyses for the provisions we are finalizing for CY 2022.

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 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule with comment period has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act).'' Accordingly, this final rule with comment period has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of the provisions of this final rule with comment period. We solicited public comments on the regulatory impact analysis in the CY 2022 OPPS/ASC proposed rule, and we address any public comments we received in this CY 2022 OPPS/ASC final rule with comment period, as appropriate.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2022, compared to CY 2021, due only to the changes to the OPPS in this final rule with comment period, would be approximately $1.27 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2022, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2022 would be approximately $82.1 billion, which is approximately $5.9 billion higher than estimated OPPS expenditures in CY 2021. Because the provisions of the OPPS are part of a final rule that is economically significant, as measured by the threshold of an additional $100 million in expenditures in 1 year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 84 of this final rule with comment period displays the distributional impact of the CY 2022 changes in OPPS payment to various groups of hospitals and for CMHCs.

We note that under our final CY 2022 policy, drugs and biologicals that are acquired under the 340B Program are paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable.

Our final policy for the CY 2022 OPPS pauses the elimination of the IPO list and adds services removed in 2021 back to the IPO list, with several codes remaining off the IPO list for CY 2022. We note that CY 2019 OPPS claims are being used in the CY 2022 OPPS ratesetting process and because the initial policy to remove codes from the IPO list was originally established in CY 2021, the effects of such policy would not be observed in our data or in the impact table. Based on our initial review of the CY 2021 claims data, we observe that most of the changes resulting from that policy have been more code-specific in nature and have had a limited broader impact. As more CY 2021 claims become available, we will continue to review that data. For a more detailed discussion of the IPO list changes, please see section IX. of this final rule with comment period.

We also note that there are changes to the ASC CPL for the CY 2022 ASC payment system. Based on initial review of the available CY 2021 claims data for ASCs, we observe that there is limited aggregate impact for codes initially added to the ASC CPL list in the CY 2021 ASC payment. In addition, we note that because CY 2019 claims data are being used in developing the impact analysis and the initial changes to the list were implemented in CY 2021, the effect of changes related to those services would not appear in this impact analysis. For a more detailed discussion of changes to the ASC CPL, please see section XIII of this final rule with comment period.

We estimate that the final update to the conversion factor and other budget neutrality adjustments would increase total OPPS payments by 2.1 percent in CY 2022. The changes to the APC relative payment weights, the changes to the wage indexes, the continuation of a payment adjustment for rural SCHs, including EACHs, the continuation of payment policy for separately payable drugs acquired under the 340B program, and the payment adjustment for cancer hospitals would not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates would change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2021 and CY 2022, considering all budget-neutral payment adjustments, changes in estimated total outlier payments, pass-through payments and the adjustment to provide separate payment for a device category, drugs, and biologicals with pass-through status expiring between December 31, 2021, and September 30, 2022, and the application of the frontier State wage adjustment, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, would increase total estimated OPPS payments by 1.6 percent.

We estimate the total increase (from changes to the ASC provisions in this final rule with comment period as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2022 compared to CY 2021, to be approximately $40 million. Because the provisions for the ASC payment system are part of a final rule that is economically significant, as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of this final rule with comment period. Tables 85 and 86 of this final rule with comment period display the redistributive impact of the CY 2022 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in This Final Rule With Comment Period

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2022 policy changes on various hospital groups. We post on the CMS website our hospital-specific estimated payments for CY 2022 with the other supporting documentation for this final rule with comment period. To view the hospital-specific estimates, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* At the website, select ''regulations and notices'' from the left side of the page and then select ''CMS–1753–FC'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for

modeling the impacts shown in Table 84. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting or impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes in order to isolate the effects associated with specific policies or updates, but any policy that changes payment could have a behavioral response. In addition, we have not made adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of the Payment Policy for Drugs and Biologicals Obtained Under the 340B Program

In section V.B. of this final rule with comment period with comment period, we discuss our policy of adjusting the payment amount for nonpass-through, separately payable drugs acquired by certain 340B participating hospitals through the 340B Program. Rural SCHs, children's hospitals, and PPS-exempt cancer hospitals continue to be excepted from this payment policy in CY 2022. Specifically, in this final rule with comment period for CY 2022, for hospitals paid under the OPPS (other than those that are excepted for CY 2022), we are paying for separately payable drugs and biologicals that are obtained with a 340B discount, excluding those on pass-through payment status and vaccines, at ASP minus 22.5 percent. Because we are continuing current Medicare payment policy for CY 2022, there is no change to the budget neutrality adjustment as a result of the 340B drug payment policy.

c. Estimated Effects of OPPS Changes on Hospitals

Table 84 shows the estimated impact of this final rule with comment period on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 84, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2022, we are continuing to pay CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs) and to pay hospitals for partial hospitalization services under APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B. of this final rule with comment period.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The IPPS market basket percentage increase applicable to the OPD fee schedule for CY 2022 is 2.7 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 2.7 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.7 percentage point for CY 2022 (which is also the productivity adjustment for FY 2022 in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45214)), resulting in the CY 2022 OPD fee schedule increase factor of 2.0 percent. We are using the OPD fee schedule increase factor of 2.0 percent in the calculation of the CY 2022 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the estimates in Table 84 of this final rule with comment period.

To illustrate the impact of the CY 2022 changes, our analysis begins with a baseline simulation model that uses the CY 2021 relative payment weights, the FY 2021 final IPPS wage indexes that include reclassifications, and the final CY 2021 conversion factor. Table 84 shows the estimated redistribution of the increase or decrease in payments for CY 2022 over CY 2021 payments to hospitals and CMHCs as a result of the following factors: The impact of the APC reconfiguration and recalibration changes between CY 2021 and CY 2022 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 2.0 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the estimated impact taking into account all payments for CY 2022 relative to all payments for CY 2021, including the impact of changes in estimated outlier payments, and changes to the pass-through payment estimate and adjustment to provide separate payment for a device category, drugs, and biologicals with pass-through status expiring between December 31, 2021, and September 30, 2022 (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are maintaining the current adjustment percentage for CY 2022. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2022 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule with comment period will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2021 and CY 2022 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the rates for CY 2022 will increase Medicare OPPS payments by an estimated 1.6 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 1.6 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 84 shows the total number of facilities (3,659), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2019 hospital outpatient and CMHC claims

data to model CY 2021 and CY 2022 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2021 or CY 2022 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this final rule with comment period. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,552), excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 39 CMHCs at the bottom of the impact table (Table 84) and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals will experience no change, with the impact ranging from a decrease of 0.1 percent to an increase of 0.1, depending on the number of beds. Rural hospitals will experience no change overall. Major teaching hospitals will experience an estimated decrease of 0.1 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration; the updates for the wage indexes with the FY 2022 IPPS post-reclassification wage indexes; the rural adjustment; the frontier adjustment, and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2021 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the CY 2022 changes in wage index policy discussed in section II.C. this final rule with comment period. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2022, as described in section II.E. of this final rule with comment period. We also did not model a budget neutrality adjustment for the cancer hospital payment adjustment because the payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2022 is 0.89, the same as the ratio that was reported for the CY 2021 OPPS/ASC final rule with comment period (85 FR 85914). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we are applying in section II.F. of this final rule with comment period.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2022 scaled weights and a CY 2021 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2021 and CY 2022.

Column 4: All Budget Neutrality Changes Combined With the Market Basket Update

Column 4 demonstrates the combined impact of all of the changes previously described and the update to the conversion factor of 2.0 percent. Overall, these changes will increase payments to urban hospitals by 2.1 percent and to rural hospitals by 2.3 percent. Both sole community hospitals and other rural hospitals receive an estimated increase of 2.3 percent.

Column 5: All Changes for CY 2022

Column 5 depicts the full impact of the final CY 2022 policies on each hospital group by including the effect of all changes for CY 2022 and comparing them to all estimated payments in CY 2021. Column 5 shows the combined budget neutral effects of Columns 2 and 3; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G. of this final rule with comment period; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIV. of this final rule with comment period); and the difference in total OPPS payments dedicated to transitional pass-through payments and the proposed adjustment to provide separate payment for the device category, drugs, and biologicals with pass-through status expiring between December 31, 2021, and September 30, 2022.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2021 update (and assumed, for modeling purposes, to be the same number for CY 2022), we included 17 hospitals in our model because they had both CY 2019 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2022 will increase payments to all facilities by 1.6 percent for CY 2022. We modeled the independent effect of all changes in Column 5 using the final relative payment weights for CY 2021 and the final relative payment weights for CY 2022. We used the final conversion factor for CY 2021 of $82.797 and the final CY 2022 conversion factor of $84.177 discussed in section II.B. of this final rule with comment period.

Column 5 contains simulated outlier payments for each year. We used the 2-year charge inflation factor used in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039) of 13.2 percent (1.13218) to increase individual costs on the CY 2019 claims, and we used the overall CCR in the April 2020 Outpatient Provider-Specific File (OPSF) with a 1-year CCR adjustment factor of 0.974495 (85 FR 59040) to estimate outlier payments for CY 2021. Using the CY 2019 claims and a 13.2 percent charge inflation factor, we currently estimate that outlier payments for CY 2021, using a multiple threshold of 1.75 and a fixed-dollar threshold of $5,300, will be approximately 1.07 percent of total payments. The estimated current outlier payments of 1.07 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 20.4 percent (1.20469) and the CCRs in the April 2020 OPSF, with an adjustment of 0.974495 multiplied by

0.974495 (86 FR 25718), to reflect relative changes in cost and charge inflation between CY 2019 and CY 2022, to model the final CY 2022 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $6,175. The charge inflation and CCR inflation factors are discussed in detail in the FY 2021 IPPS/LTCH PPS final rule (84 FR 45542).

Overall, we estimate that facilities will experience an increase of 1.6 percent under this final rule with comment period in CY 2022 relative to total spending in CY 2021. This projected increase (shown in Column 5) of Table 84 reflects the 2.0 percent OPD fee schedule increase factor, minus 0.32 percent for the change in the pass-through payment estimate between CY 2021 and CY 2022 and the adjustment to provide separate payment for the device category, drugs, and biologicals with pass-through status expiring between December 31, 2021, and September 30, 2022, minus the difference in estimated outlier payments between CY 2021 (1.07 percent) and CY 2022 (1.0 percent). We estimate that the combined effect of all proposed changes for CY 2022 will increase payments to urban hospitals by 1.6 percent. Overall, we estimate that rural hospitals will experience a 1.6 percent increase as a result of the combined effects of all the proposed changes for CY 2022.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 1.4 percent for major teaching hospitals and an increase of 1.7 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 1.6 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 1.6 percent, proprietary hospitals will experience an increase of 1.7 percent, and governmental hospitals will experience an increase of 1.7 percent.

BILLING CODE 4120–01–P

TABLE 84: Estimated Impact of the CY 2022 Changes for the Hospital Outpatient Prospective Payment System

		(1)	(2)	(3)	(4)	(5)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**All Changes**
ALL PROVIDERS *		3,659	0.0	0.1	2.1	1.6
ALL HOSPITALS		3,552	0.0	0.1	2.1	1.6
	(excludes hospitals held harmless and CMHCs)					
URBAN HOSPITALS		2,803	0.0	0.1	2.1	1.6
	LARGE URBAN	1,448	0.0	0.1	2.1	1.7
	(GT 1 MILL.)					
	OTHER URBAN	1,355	0.0	0.1	2.1	1.5
	(LE 1 MILL.)					
RURAL HOSPITALS		749	0.0	0.3	2.3	1.6
	SOLE COMMUNITY	368	0.0	0.4	2.3	1.5
	OTHER RURAL	381	0.0	0.2	2.3	1.7
BEDS (URBAN)						
	0 - 99 BEDS	958	0.1	0.2	2.2	1.7
	100-199 BEDS	786	0.1	0.1	2.2	1.7
	200-299 BEDS	447	0.1	0.2	2.2	1.7
	300-499 BEDS	386	0.0	0.2	2.2	1.6
	500 + BEDS	226	-0.1	-0.1	1.8	1.4
BEDS (RURAL)						
	0 - 49 BEDS	327	0.1	0.3	2.4	1.6
	50- 100 BEDS	256	0.0	0.3	2.4	1.5
	101- 149 BEDS	90	-0.1	0.2	2.1	1.4
	150- 199 BEDS	38	0.0	0.4	2.4	1.8
	200 + BEDS	38	0.0	0.2	2.2	1.8
REGION (URBAN)						
	NEW ENGLAND	132	0.0	0.0	2.0	1.6

		(1)	(2)	(3)	(4)	(5)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**All Changes**
	MIDDLE ATLANTIC	326	-0.1	0.1	2.0	1.6
	SOUTH ATLANTIC	455	0.0	0.3	2.2	1.8
	EAST NORTH CENT.	440	0.0	-0.2	1.8	1.4
	EAST SOUTH CENT.	163	0.0	-0.1	1.9	1.5
	WEST NORTH CENT.	186	0.0	0.9	2.9	1.5
	WEST SOUTH CENT.	474	0.1	-0.3	1.7	1.3
	MOUNTAIN	213	0.0	0.3	2.3	1.5
	PACIFIC	366	0.0	0.1	2.2	1.7
	PUERTO RICO	48	0.2	-0.5	1.8	1.4
REGION (RURAL)						
	NEW ENGLAND	20	-0.1	-0.2	1.7	1.2
	MIDDLE ATLANTIC	50	0.0	0.0	2.1	1.7
	SOUTH ATLANTIC	113	0.1	0.5	2.6	2.2
	EAST NORTH CENT.	119	0.0	-0.3	1.8	1.4
	EAST SOUTH CENT.	146	0.0	-0.2	1.8	1.4
	WEST NORTH CENT.	91	-0.1	1.1	3.0	1.4
	WEST SOUTH CENT.	140	0.2	0.6	2.8	2.4
	MOUNTAIN	47	-0.1	2.1	4.0	1.4
	PACIFIC	23	-0.1	-0.4	1.6	1.2
TEACHING STATUS						
	NON-TEACHING	2,385	0.1	0.2	2.2	1.7
	MINOR	792	0.0	0.2	2.2	1.6
	MAJOR	375	-0.1	0.0	1.8	1.4
DSH PATIENT PERCENT						
	0	13	0.3	-0.1	2.1	1.6
	GT 0 - 0.10	266	0.0	0.1	2.2	1.6

		(1)	(2)	(3)	(4)	(5)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**All Changes**
	0.10 - 0.16	240	0.1	0.0	2.1	1.6
	0.16 - 0.23	579	0.1	0.1	2.2	1.6
	0.23 - 0.35	1,099	0.0	0.2	2.1	1.6
	GE 0.35	897	-0.1	0.1	2.0	1.6
	DSH NOT AVAILABLE **	458	0.1	0.0	2.2	1.7
URBAN TEACHING/DSH						
	TEACHING & DSH	1,048	0.0	0.1	2.0	1.5
	NO TEACHING/DSH	1,304	0.1	0.1	2.2	1.7
	NO TEACHING/NO DSH	13	0.3	-0.1	2.1	1.6
	DSH NOT AVAILABLE2	438	0.1	0.0	2.1	1.7
TYPE OF OWNERSHIP						
	VOLUNTARY	1,973	0.0	0.2	2.2	1.6
	PROPRIETARY	1,131	0.2	0.1	2.3	1.7
	GOVERNMENT	448	-0.1	-0.2	1.7	1.7
CMHCs		39	0.4	-1	1.4	1.1

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all CY 2022 OPPS policies and compares those to the CY 2021 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the final FY 2022 hospital inpatient wage index. The rural SCH adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.0000 because the CY 2022 target payment-to-cost ratio is the same as the CY 2021 PCR target (0.89)

Column (4) shows the impact of all budget neutrality adjustments and the addition of the 2.0 percent OPD fee schedule update factor (2.7 percent reduced by 0.7 percentage points for the productivity adjustment).

Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, adjustment to provide separate payment for the device category, drugs, and biologicals with pass-through status
expiring between December 31, 2021 and September 30, 2022, and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have added the frontier adjustment to Column 3 in this table.

These 3,659 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

		(1)	(2)	(3)	(4)	(5)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**All Changes**
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.						

BILLING CODE 4120–01–C

d. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 84 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2021, CMHCs are paid under APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this APC policy assuming CMHCs will continue to provide the same number of days of PHP care as seen in the CY 2019 claims used for rate setting in the final rule. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. We estimate that CMHCs will experience an overall 1.1 percent increase in payments from CY 2021 (shown in Column 5). We note that this includes the trimming methodology as well as the proposed CY 2022 geometric mean costs used for developing the PHP payment rates described in section VIII.B. of this final rule with comment period.

Column 3 shows the estimated impact of adopting the final FY 2022 wage index values will result in a decrease of 1.0 percent to CMHCs. Column 4 shows that combining the OPD fee schedule increase factor, along with final changes in APC policy for CY 2022 and the final FY 2022 wage index updates, will result in an estimated increase of 1.4 percent. Column 5 shows that adding the changes in outlier and pass-through payments will result in a total 1.1 percent increase in payment for CMHCs. This reflects all final changes for CMHCs for CY 2022.

e. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments will rise and will decrease for services for which the OPPS payments will fall. For further discussion of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this final rule with comment period. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be 18.2 percent for all services paid under the OPPS in CY 2022. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the final CY 2022 comprehensive APC payment policy discussed in section II.A.2.b. of this final rule. We note that the individual payments, and therefore copayments, associated with services may differ based on the setting in which they are furnished. However, at the aggregate system level, because site of service changes related to the IPO list and ASC CPL for certain procedures are more service specific and because the overall impact has been limited in nature, we do not currently observe significant impact on beneficiary coinsurance as a result of those policies.

f. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XIII of the final rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs will be affected by the changes in the final rule.

g. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of $1.27 billion in program payments for OPPS services furnished in CY 2022. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the changes in the final rule would increase these Medicaid beneficiary payments by approximately $80 million in CY 2022. Currently, there are approximately 10 million dual-eligible beneficiaries, which represent approximately thirty percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking 30 percent of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 57 percent Federal payments and 43 percent state payments. Therefore, for the estimated $80 million Medicaid increase, approximately $45 million will be from the Federal Government and $35 million would be from state governments.

h. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and the reasons for our selected alternatives are discussed throughout the final rule.

- Alternatives Considered for the Claims Data used in OPPS and ASC Ratesetting due to the PHE.

We refer readers to section X.E. of the CY 2022 OPPS/ASC proposed rule with comment period for a discussion of our proposed policy of generally using claims, cost report, and other data prior to the PHE. We note that in that section we discuss the alternative proposal we considered regarding applying the standard ratesetting process, in particular the selection of data used, which would include claims and cost report data including the timeframe of the PHE. We note that there are potential issues related to that data, including the effect of the PHE on the OPPS relative payment weights and the service mix applied in the budget neutrality process; and, therefore, our primary proposal was to use CY 2019 claims and cost report data generally in CY 2022 OPPS ratesetting. In this final rule, as discussed in section X.E., we are finalizing a policy of using the CY 2019 claims data in CY 2022 OPPS ratesetting, while allowing for certain exceptions in which we would use CY 2020 claims in consideration of factors such as APC placement.

We note that these policy considerations also have ASC implications since the relative weights for certain surgical procedures

performed in the ASC setting are developed based on the OPPS relative weights and claims data.

2. Estimated Effects of CY 2022 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII. of this final rule with comment period, we are setting the CY 2022 ASC relative payment weights by scaling the final CY 2022 OPPS relative payment weights by the final ASC scalar of 0.8552. The estimated effects of the final updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 85 and 86.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which, in CY 2019, we adopted a policy to be the hospital market basket for CY 2019 through CY 2023) after application of any quality reporting reduction be reduced by a productivity adjustment. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (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). For ASCs that fail to meet their quality reporting requirements, the CY 2022 payment determinations will be based on the application of a 2.0 percentage point reduction to the annual update factor, which will be the hospital market basket for CY 2022. We calculated the CY 2022 ASC conversion factor by adjusting the CY 2021 ASC conversion factor by 0.9997 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2021 and CY 2022 and by applying the CY 2022 productivity-adjusted hospital market basket update factor of 2.0 percent (which is equal to the projected hospital market basket update of 2.7 percent reduced by a productivity adjustment of 0.7 percentage point). The CY 2022 ASC conversion factor is $49.916 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the final changes for CY 2022 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2019 and CY 2022 with precision. We believe the net effect on Medicare expenditures resulting from the final CY 2022 changes will be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups, as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs will experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the final update to the CY 2022 payments will depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion includes tables that display estimates of the impact of the final CY 2022 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2019 claims data. Table 85 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2021 payments to estimated CY 2022 payments, and Table 86 shows a comparison of estimated CY 2021 payments to estimated CY 2022 payments for procedures that we estimate will receive the most Medicare payment in CY 2021.

In Table 85, we have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 85.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—Estimated CY 2021 ASC Payments were calculated using CY 2019 ASC utilization data (the most recent full year of ASC utilization) and CY 2021 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2021 ASC payments.
- Column 3—Estimated CY 2022 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that is attributable to final updates to ASC payment rates for CY 2022 compared to CY 2021.

As shown in Table 85, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC payment rates for CY 2022 will result in a 1-percent decrease in aggregate payment amounts for eye and ocular adnexa procedures, a 2-percent increase in aggregate payment amounts for nervous system procedures, 2-percent increase in aggregate payment amounts for digestive system procedures, a 3-percent increase in aggregate payment amounts for musculoskeletal system procedures, a 6-percent increase in aggregate payment amounts for cardiovascular system procedures, and a 3-percent increase in aggregate payment amounts for genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and proposed changes in policy. In general, spending in each of these categories of services is increasing due to the 2.0 percent proposed payment rate update. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than a 2.0 percent increase, depending on if payment weights in the OPPS APCs that correspond to the applicable services increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 6-percent increase in proposed aggregate cardiovascular procedure payments.

The increase in payment rates for cardiovascular procedures as a result of increased device-intensive designations is further increased by the final 2.0 percent ASC rate update for these procedures. Conversely, we estimate a 1-percent decrease in proposed aggregate eye and ocular adnexa procedures related to certain high-volume procedures no longer being assigned device-intensive status as well as estimates in utilization for certain new cataract removal and device insertion procedures. For estimated changes for selected procedures, we refer readers to Table 85 provided later in this section.

TABLE 85: ESTIMATED IMPACT OF THE CY 2022 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2022 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2021 ASC Payments (in Millions) (2)	Estimated CY 2022 Percent Change (3)
Total	$5,682	2
Eye	$1,918	-1
Nervous System	$1,211	2
Gastrointestinal	$948	2
Musculoskeletal	$727	3
Cardiovascular	$280	6
Genitourinary	$213	3

Table 85 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2022. The table displays 30 of the procedures receiving the greatest estimated CY 2021 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2021 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2021 ASC Payments were calculated using CY 2019 ASC utilization (the most recent full year of ASC utilization) and the CY 2021 ASC payment rates. The estimated CY 2021 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2022 Percent Change reflects the percent differences between the estimated ASC payment for CY 2021 and the estimated payment for CY 2022 based on the final update.

BILLING CODE 4120–01–P

TABLE 86 : ESTIMATED IMPACT OF THE FINAL CY 2022 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2021 ASC Payment (in millions) (3)	Estimated CY 2022 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,293	0
63685	Insrt/redo spine n generator	$293	2
45380	Colonoscopy and biopsy	$251	3
45385	Colonoscopy w/lesion removal	$187	3
63650	Implant neuroelectrodes	$187	2
43239	Egd biopsy single/multiple	$186	2
64483	Njx aa&/strd tfrm epi l/s 1	$122	3
66982	Xcapsl ctrc rmvl cplx wo ecp	$96	-1
64635	Destroy lumb/sac facet jnt	$86	3
64493	Inj paravert f jnt l/s 1 lev	$79	3
36902	Intro cath dialysis circuit	$78	2
29827	Sho arthrs srg rt8tr cuf rpr	$76	3
66821	After cataract laser surgery	$67	2
64590	Insrt/redo pn/gastr stimul	$63	2
C9740	Cysto impl 4 or more	$58	2
22869	Insj stablj dev w/o dcmprn	$58	3
62323	Njx interlaminar lmbr/sac	$55	3
G0105	Colorectal scrn; hi risk ind	$53	2
15823	Revision of upper eyelid	$41	2
45378	Diagnostic colonoscopy	$39	2
G0121	Colon ca scrn not hi rsk ind	$39	2
64721	Carpal tunnel surgery	$37	3
63655	Implant neuroelectrodes	$32	3
65820	Relieve inner eye pressure	$30	3
62362	Implant spine infusion pump	$28	2
67042	Vit for macular hole	$28	2
29881	Knee arthroscopy/surgery	$28	3
64490	Inj paravert f jnt c/t 1 lev	$28	3
64561	Implant neuroelectrodes	$28	2
G0260	Inj for sacroiliac jt anesth	$27	3

c. Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the CY 2022 update to the ASC payment system will be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the new procedures designated as office-based for CY 2022. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the hospital inpatient deductible since the statute requires that OPPS copayment amounts not exceed the hospital inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the hospital inpatient deductible and, therefore, the OPPS copayment amount for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPPS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the

nonfacility practice expense based amount payable under the PFS. For those additional procedures that we designate as office-based in CY 2022, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the PFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

3. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget website at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a004/a-4.html*), we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this final rule with comment period. The first accounting statement, Table 87, illustrates the classification of expenditures for the CY 2022 estimated hospital OPPS incurred benefit impacts associated with the final CY 2022 OPD fee schedule increase. The second accounting statement, Table 88, illustrates the classification of expenditures associated with the 2.0 percent CY 2022 update to the ASC payment system, based on the provisions of the final rule with comment period and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers.

TABLE 87: ACCOUNTING STATEMENT: CY 2022 Estimated Hospital OPPS Transfers from CY 2021 to CY 2022 Associated with the CY 2022 Hospital Outpatient OPD Fee Schedule Increase

Category	Transfers
Annualized Monetized Transfers	$1,270 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS

TABLE 88: ACCOUNTING STATEMENT: Classification of Estimated Transfers from CY 2021 to CY 2022 as a Result of the CY 2022 Update to the ASC Payment System

Category	Transfers
Annualized Monetized Transfers	$80 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$80 million

TABLE 89: Estimated Costs in CY 2022

CATEGORY	Costs
Burden	$4.54 million*
Regulatory Familiarization	$17.057 million**

*The annual estimate includes the impact of OQR and ASCQR program, vaccination coverage data collection across hospitals and ASCs, burden estimate for RO model, and burden reduction for State forensic hospitals.
** Regulatory familiarization costs occur upfront only.

TABLE 90 : Accounting Statement Estimated Impacts for the Radiation Oncology Model

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Transfers				
Annualized Monetized ($million/year)	-$27 million	2020	7%	2022 – 2026
	-$29 million	2020	3%	2022 – 2026
From Whom to Whom	From the Federal Government to healthcare providers			

BILLING CODE 4120–01–C

4. Effects of Changes in Requirements for the Hospital OQR Program

a. Background

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59492 through 59494), for the previously estimated effects of changes to the Hospital Outpatient Quality Reporting (OQR) Program for the CY 2018, CY 2019, and CY 2021 payment determinations. Of the 3,163 hospitals that met eligibility requirements for the CY 2021 payment determination, we determined that 77 hospitals did not meet the requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor.

b. Impact of CY 2022 OPPS/ASC Finalized Policies

We anticipate that some of the CY 2022 Hospital OQR Program finalized policies will impact the number of facilities that will receive payment reductions. In this final rule, we are finalizing our proposals to: (1) Adopt the COVID–19 Vaccination Coverage Among HCP measure (OP–38), beginning with the CY 2022 reporting period; (2) adopt the Breast Screening Recall Rates measure (OP–39), beginning with the CY 2022 reporting period; (3) adopt the STEMI eCQM (OP–40), beginning as a voluntary measure with the CY 2023 reporting period, and then as a mandatory measure beginning with the CY 2024 reporting period; (4) require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey measures (OP–37a–e), with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination; (5) remove the Fibrinolytic Therapy Received Within 30 Minutes measure (OP–2), effective with the CY 2023 reporting period; (6) remove the Median Time to Transfer to Another Facility for Acute Coronary Intervention measure (OP–3), effective with the CY 2023 reporting period; (7) remove the option for hospitals to send medical records to the validation contractor via paper and removable media and require electronic submission; (8) reduce the number of days hospitals have to submit medical records to the CDAC from 45 days to 30 days; (9) enhance the targeting criteria used for hospital selection by adopting criteria currently used in inpatient data validation by adding the following criteria: (a) Having a lower bound confidence interval score of 75 percent or less; and (b) having not been selected in the previous 3 years; (10) extend our existing ECE policy to apply to eCQMs, to further align with the Hospital Inpatient Quality Reporting (IQR) Program; and (11) require use of technology updated consistent with 2015 Edition Cures Update criteria beginning with the CY 2023 reporting period. We are also finalizing our proposal with modification to require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure (OP–31) beginning with the CY 2025 reporting period/CY 2027 payment determination instead of the CY 2023 reporting period/CY 2025 payment determination.

As shown in Table 81 in section XXII.B.4. (Collection of Information) of this final rule with comment period, we estimate a total information collection burden decrease for 3,300 OPPS hospitals of −73,344 hours at a cost of −$3,109,786 annually associated with our proposed policies and updated burden estimates across a 5-year period from the CY 2022 reporting period/CY 2024 payment determination through the CY 2027 reporting period/CY 2029 payment determination, compared to our currently approved information collection burden estimates. We refer readers to section XXII.B. of this final rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Hospital OQR Program. As discussed in this section of the final rule, we are finalizing policies that will have additional economic impact. The finalized policies not discussed in this section are believed to have no further economic impact beyond information collection burden.

In section XV.B.4.a. of this final rule with comment period, we are finalizing the adoption of the COVID–19 Vaccination Coverage Among HCP measure (OP–38) beginning with the CY 2022 reporting period/CY 2024 payment determination. Hospitals will submit data through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based system maintained by the CDC and provided free. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package currently approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[605] Although the burden associated with the COVID–19 Vaccination Coverage Among HCP measure (OP–38) is not accounted for under the CDC PRA 0920–1317 or 0920–0666, the cost and burden information is included here. We estimate that it will take each hospital on average approximately 1 hour per month to report data for the COVID–19 Vaccination Coverage Among HCP measure (OP–38) which may vary between 45 minutes and 1 hour and 15 minutes to enter this data into NHSN. Beginning with the CY 2022 reporting period/FY 2024 payment determination, hospitals will incur an additional annual burden between 9 hours (0.75 hours/month × 12 months) and 15 hours (1.25 hours/month × 12 months) per hospital and between 29,700 hours (9 hours/hospital × 3,300 hospitals) and 49,500 hours (15 hours/hospital × 3,300 hospitals) for all hospitals. Each hospital will incur an estimated cost of between $323.28 (9 hours × $35.92/hr) and $538.80 annually (15 hours × $35.92/hr).[606] The estimated cost across all 3,300 hospitals will be between $1,066,824 ($323.28/hospital × 3,300 hospitals) and $1,778,040 ($538.80/hospital × 3,300 hospitals) annually thereafter. We recognize that many healthcare facilities are also reporting other COVID–19 data to HHS. We believe the benefits of reporting data on the COVID–19 Vaccination Coverage Among HCP measure (OP–38) outweigh the associated costs of reporting. We did not receive any comments on the estimated time to collect data and enter it into the NHSN as well as any additional costs associated with this measure.

In section XV.B.4.c. of this final rule with comment period, we are finalizing the adoption of the STEMI eCQM (OP–40). Similar to the FY 2019 IPPS/LTCH PPS final rule, we believe that costs associated with adoption of eCQMs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining Program requirements, such as maintaining measure specifications in hospitals EHR systems for all of the eCQMs available

[605] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

[606] *https://www.bls.gov/oes/current/oes436013.htm.* Accessed on April 13, 2021. The adjusted hourly wage rate of $35.92/hr includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

for use in the Hospital OQR Program (83 FR 41771).

As described in section XV.D.6. of this final rule with comment period, we are finalizing certification requirements requiring the use of the 2015 Edition Cures Update for eCQMs beginning with the CY 2025 payment determination. We expect this finalization to have no impact on information collection burden for the Hospital OQR Program because this policy does not require hospitals to submit new data to CMS. With respect to any costs unrelated to data submission, although this finalized policy will require some investment in systems updates, the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs) previously finalized a requirement that hospitals use the 2015 Edition Cures Update for eCQMs (85 FR 84818 through 84825). Because all hospitals participating in the Hospital OQR Program are subsection (d) hospitals that also participate in the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs), we do not anticipate any additional costs as a result of the finalization of this policy. This is because the burden and costs involved in updating to the 2015 Edition Cures Update is the same regardless of whether the technology is used for eCQMs. Therefore, we believe that the Medicare Promoting Interoperability Program has already addressed the additional costs unrelated to data submission through their previously finalized requirements.

In section XV.D.9.c. of this final rule with comment period, we are finalizing the proposal to reduce the number of days hospitals have to submit medical records to the CDAC from 45 days to 30 days. In previous years, charts were requested by the CMS CDAC contractor and hospitals were given 45 days from the date of the request to submit the requested records. This may be an additional administrative burden to hospitals selected for validation. However, this deadline is in line with the Hospital IQR Program's validation policy, the large majority of hospitals that have participated in Hospital OQR Program data validation efforts have submitted their records prior to 30 days in the current process, and outpatient records typically contain significantly fewer pages than the inpatient records. Therefore, we believe the impact of finalizing this policy to be minimal.

5. Effects of Requirements for the ASCQR Program

a. Background

In section XVI. of this final rule with comment period, we discuss our finalized policies affecting the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. For the CY 2021 payment determination, all 6,811 ASCs that met eligibility requirements for the ASCQR Program received the annual payment update due to data submission requirements being excepted under the ASCQR Program's Extraordinary Circumstances Exceptions policy in consideration of the COVID–19 public health emergency.[607]

b. Impact of CY 2022 OPPS/ASC Finalized Policies

In section XVI. of this final rule with comment period, we are finalizing our proposals to: (1) Require four patient safety outcome measures beginning with the CY 2023 reporting period/CY 2025 payment determination: (a) Patient Burn (ASC–1); (b) Patient Fall (ASC–2); (c) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC–3); and (d) All-Cause Hospital Transfer/Admission (ASC–4); (2) add two additional data collection survey modes of OAS CAHPS measures collection to the existing three modes of collection and provide survey administration requirements; and (3) adopt the COVID–19 Vaccination Coverage Among HCP measure (ASC–20), beginning with the CY 2022 reporting period/CY 2024 payment determination. We note that we are finalizing with modification our proposals to: (1) Require the Cataracts: Improvement in Patient's Visual Function within 90 days Following Cataract Surgery (ASC–11) measure beginning with the CY 2025 reporting period/CY 2027 payment determination instead of the CY 2023 reporting period/CY 2025 payment determination; and (2) require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey measures (ASC–15 a–e) with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2025 reporting period/CY 2027 payment determination instead of the CY 2024 reporting period/CY 2026 payment determination.

As shown in Tables 82 and 83 in section XXII.C.3.e. (Collection of Information) of this final rule with comment period, we estimate a total information collection burden increase for 4,646 ACSs of +67,085 hours at a cost of +$2,844,404 annually associated with our proposed policies and updated burden estimates across a 4 year period from the CY 2023 reporting period/CY 2025 payment determination through the CY 2026 reporting period/CY 2028 payment determination, compared to our currently approved information collection burden estimates. We refer readers to section XXIII.C. of the preamble of this final rule with comment period (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the ASCQR Program.

In section XVI.B.3.a. of this final rule with comment period, we are finalizing the adoption of the COVID–19 Vaccination Coverage Among HCP measure (ASC–20) beginning with the CY 2022 reporting period/CY 2024 payment determination. The impacts and benefits associated with finalizing this proposal are comparable to those previously discussed for the same measure being finalized in the Hospital OQR Program. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package currently approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[608] Although the burden associated with the COVID–19 Vaccination Coverage Among HCP measure (ASC–20) is not accounted for under the CDC PRA 0920–1317 or 0920–0666, the cost and burden information is included here. We estimate that each ASC will spend on average approximately 1 hour per month to collect data for the COVID–19 Vaccination Coverage Among HCP measure (ASC–20) and enter it into NHSN. We have estimated that the associated burden is comprised of administrative hours and wages. We believe an Administrative Assistant will spend between 45 minutes and 1 hour and 15 minutes to enter this data into NHSN. Beginning with the CY 2022 reporting period/FY 2024 payment

[607] Centers for Medicare & Medicaid Services. COVID–19 Quality Reporting Programs Guidance Memo. Available at *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

[608] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

determination, ASCs will incur an additional annual burden between 9 hours (0.75 hours/month × 12 months) and 15 hours (1.25 hours/month × 12 months) per ASC and between 41,814 hours (9 hours/hospital × 4,646 ASCs) and 69,690 hours (15 hours/hospital × 4,646 ASCs) for all ASCs. Each ASC will incur an estimated cost of between $323.28 (9 hours × $35.92/hour) and $538.80 annually (15 hours × $35.92/hour). The estimated cost across all 4,646 ASCs will be between $1,501,959 ($323.28/ASC × 4,646 ASCs) and $2,503,265 ($538.80/ASC × 4,646 ASCs) annually thereafter. We did not receive comments on the estimated time to collect data and enter it into the NHSN as well as any additional costs associated with this measure.

6. Effects of Requirements for the RO Model

a. Financial Impact

We have examined the impact of this final rule as required by Executive Order 12866 and other laws and Executive Orders, requiring economic analysis of the effects of final rules. We are finalizing a different model performance period than was finalized in the Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs final rule with comment period (85 FR 85866) (hereinafter referred to as ''CY 2021 OPPS/ASC final rule''). We are also finalizing an updated baseline period, lower discounts, the removal of brachytherapy from the included modalities, and the removal of liver cancer from the list of included cancer types finalized under the publication of the Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures Final Rule (Specialty Care Models final rule) (85 FR 61114) on September 29, 2020. We have updated our net estimate of the RO Model impact to reflect all of the modifications to the RO Model design in this final rule. Accordingly, we have prepared an RIA that, to the best of our ability, reflects the economic impact of the policies contained in this final rule.

b. Statement of Need for the Radiation Oncology (RO) Model

In the CY 2021 OPPS/ASC proposed rule (86 FR 42350), we noted that the statement of need for the RO Model described in the Specialty Care Models final rule (85 FR 61347) and the CY 2021 OPPS/ASC final rule (85 FR 86296) remains unchanged.

c. Impact of RO Model

Based on the finalized policy of the Specialty Care Models final rule (85 FR 61114), we expected a savings of $230 million for Medicare over a 5-year model performance period. The CY 2021 OPPS/ASC final rule with comment period (85 FR 86296) included a savings estimate of $220 million for Medicare over a 4.5-year model performance period. We now expect that the finalized modifications included in this final rule, which include a change to a revised model performance period that begins January 1, 2022 and ends December 31, 2026, a revised baseline period, the removal of brachytherapy and liver cancer, as well as the lowered discounts, will reduce savings to $150 million for Medicare over the course of the five-year model performance period.

d. Anticipated Effects

(1) Scale of the Radiation Oncology (RO) Model

As we stated in the CY 2022 OPPS/ASC proposed rule (86 FR 42350), revising the model performance period to begin January 1, 2022 will not affect the number of PGPs or HOPDs we expect to furnish RT services in the simulated selected CBSAs. We currently expect the model performance period that begins January 1, 2022, and ends December 31, 2026, will include approximately 282,000 episodes, 250,000 beneficiaries, and $4.6 billion in total episode spending of allowed charges over the model performance period. The revision was primarily the result of updated FFS Part B enrollment projections, slower assumed growth in RT episodes per patient, and minor technical changes to the projection process than was assumed in the Specialty Care Models final rule in September 2020.

(2) Effects of the RO Model on the Medicare Program

(a) Overview

Under the current FFS payment system, RT services are paid on a per service basis to both PGPs (including freestanding radiation therapy centers) and HOPDs through the PFS and the OPPS, respectively. The RO Model is a mandatory model designed to test a prospectively determined episode payment for RT services furnished to Medicare beneficiaries during episodes initiated between January 1, 2022 and December 31, 2026.

(b) Data and Methods

Similar to the analysis performed for the regulatory impact analysis for the Specialty Care Models final rule (85 FR 61347) and the CY 2022 OPPS/ASC proposed rule (86 FR 42350), a stochastic simulation based on the policies in this final rule was created to estimate the financial impacts of the RO Model relative to baseline expenditures.

(c) Medicare Estimate

Table 91 summarizes the estimated impact of the RO Model with a model performance period that begins January 1, 2022, and ends December 31, 2026. We estimate that on net the Medicare program would save $150 million over the 5-year model performance period. Changes in the estimated impacts for this policy relative to those presented in the CY2022 OPPS/ASC proposed rule (86 FR 42350 through 42352) generally reflect updated economic assumptions, no material technical changes were made to our projection methodology. As in the Specialty Care Models final rule (85 FR 61350) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86297), this is the net Medicare Part B impact that includes both Part B premium and Medicare Advantage United States Per Capita Costs (MA USPCC) rate financing interaction effects. This estimate excludes changes in beneficiary cost sharing liability to the extent it is not a Federal outlay under the policy.

As codified at § 512.280(d), the APM incentive payment will apply only to the professional episode payment amounts and not the technical episode payment amounts. Moreover, due to the 2-year lag in Quality Payment Program performance and payment periods and quality data reporting starting in 2022, APM incentive payments will only be made during 2024. We projected that 80 percent (down from 83 percent as projected in the Specialty Care Models final rule) of physician participants (measured by unique NPI) will receive the APM incentive payment under the Quality Payment Program for 2022.

Complete information regarding the data sources and underlying methodology used to determine amounts for reconciliation were not available at the time of this forecast. Like in the Specialty Care Models final rule, in the case of the incomplete payment withhold, we assumed CMS retains payment only in the event that offsetting payment errors were made elsewhere. Moreover, past CMS experience in the and Hospital Value-Based Purchasing (VBP) and Merit-based Incentive Payment System (MIPS) programs that included value-based reporting requirements has shown a low rate of non-compliance on the part of providers and suppliers. Given the

limited spending being withheld, scoring criteria (that is the use of the Aggregate Quality Score (AQS) and its application to the quality withhold, as finalized at 85 FR 61226 through 61231), and specified timeframes involved, we assume that quality and patient experience withholds, on net, would have a negligible financial impact to CMS.

A key assumption underlying the impact estimate is that the volume and intensity (V&I) of the bundled services per episode remains unchanged between the baseline period and when bundled RO payments are made. If V&I were to decrease by 1.0 percent annually for the bundled services absent the RO Model, then we estimated the RO Model to be approximately budget neutral between January 1, 2022 and December 31, 2026. Similarly, if V&I increases by 1.0 percent annually then net Medicare outlays would be reduced by $280 million for this projection period. Although V&I growth from 2014 through 2019 fell within this 1.0 percent range and did not exhibit a secular trend, actual experience may differ.

Please also note that due to the current public health crisis caused by the COVID–19 virus, the forecasted impacts for the RO Model are subject to an additional level of uncertainty. The duration of the current COVID–19 pandemic, its severity, and future policy measures taken in response are variables that are significant but unknown at this time. This forecast assumes that Medicare FFS billing and treatment patterns for beneficiaries observed during the 2017 to 2019 baseline period have resumed by the start of 2022.To the extent that this assumption does not hold, actual experience may vary significantly. Table 91 summarizes our estimated impacts of this final rule with comment period.

TABLE 91: Estimates of Medicare Program Savings (Millions $) for Radiation Oncology Model (Starting January 1, 2022)

	Year of Model					
	2022	**2023**	**2024**	**2025**	**2026**	**Total***
Net Impact to Medicare Program Spending	-20	-30	-20	-40	-40	-150
Changes to Incurred FFS Spending	-20	-20	-20	-30	-30	-120
Changes to MA Capitation Payments	0	-20	-20	-20	-30	-80
Part B Premium Revenue Offset	0	10	10	10	10	50
Total APM Incentive Payments	0	0	10	0	0	10
Episode Allowed Charges	830	860	900	930	970	4,490
Episode Medicare Payment	650	670	700	730	750	3,500
Total Number of Episodes	53,300	54,900	56,400	58,000	59,600	282,200
Total Number of Beneficiaries	51,900	53,500	54,900	56,500	58,100	250,200

*Negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase.

*Totals may not sum due to rounding and from beneficiaries that have cancer treatment spanning multiple years.

e. Effects on RO Participants

We believe that the finalized changes will not affect the total cost of learning the billing system for the RO Model but will, however, affect the burden estimate for reporting quality measures and clinical data elements.

We believe the burden estimate for quality measure and clinical data element reporting requirements that is provided for Small Businesses in CY 2021 OPPS/ASC final rule with comment period (85 FR 86297) apply to RO participants that are not considered small entities. The burden estimate for collecting and reporting quality measures and clinical data for the RO Model may be equal to or less than that for small businesses, which we estimated to be approximately $1,845 per entity per year based on 2020 wages. Since we estimated approximately 500 Professional participants and Dual participants will be collecting and reporting this data, the total annual burden estimate for collecting and reporting quality measures and clinical data is approximately $922,500 for a total of $4,612,500 over 5 years, and this remains unchanged in this final rule.

Like the Medicare Specialty Models final rule (85 FR 61358), this final rule with comment period affects: (1) Radiation oncology PGPs that furnish RT services in both freestanding radiation therapy centers and HOPDs; (2) PGPs that furnish RT services only in HOPDs; (3) PGPs that are categorized as freestanding radiation therapy centers; and (4) HOPDs. Based on the finalized modifications to the design of the RO Model, we believe that on average, Medicare FFS payments to PGPs (including freestanding radiation therapy centers) will increase by 6.3 percent and Medicare FFS payments to HOPDs will be reduced by 9.9 percent over the life of the Model as shown in Table 92 below. This estimate is made under the assumption of no changes to PFS clinical labor rates as outlined in the CY 2022 PFS proposed rule (CMS–1751–P) occurring. To the extent the PFS were to finalize clinical labor RVU adjustment policies outlined in the recent proposed rule, we would expect PGPs to see an average increase of 10.2 percent and HOPDs a decrease of 11.3 percent over the lifetime of the RO Model.

Under Medicare FFS, PGPs that furnish RT professional services to HOPDS are largely paid through the PFS and freestanding radiation therapy centers are largely paid through the PFS for both RT professional and technical services. In contrast, HOPDs are paid through the OPPS for RT technical services. Unit-cost increases under the PFS are projected to be lower than under the OPPS over time. This means that when the payment rates of the PFS and the OPPS (along with the volume of HCPCS codes of non-participant episodes) are used to determine the trend factors for each cancer type, PGPs (including freestanding radiation therapy centers), on average, are projected to experience incremental gains to payment over time, while HOPDs, on average, are projected to experience incremental losses to payment over time. In other words, the impact for HOPDs and PGPs depends on a combination of the RO Model's discount factor and the RO Model's trend factor, which blends the latest OPPS and PFS payment rates based on their historical claims volume in non-participating RT providers and RT suppliers. Given that PFS rates are not expected to increase between 2019 and 2026 and the OPPS rates are, blending these rates together leads to an average increase in allowed charges expected for PGPs (including freestanding radiation therapy centers) and an average decrease in allowed charges expected for HOPDs (because HOPDs that are RO participants will not get the full OPPS rate increase but rather a trend that blends OPPS with PFS). Table 92 provides additional information about the expected impacts by year:

TABLE 92: Radiation Oncology Model PGP (including freestanding radiation therapy centers) vs HOPD Allowed Charge Impacts 2022 to 2026 as compared to those not participating in the RO Model

% Impact	2022	2023	2024	2025	2026	2022 to 2026
PGP (including freestanding radiation therapy centers)	3.1%	4.5%	6.0%	7.4%	8.9%	6.3%
HOPD	-7.8%	-8.8%	-9.6%	-10.6%	-11.6%	-9.9%

We believe that this impact would be reduced for smaller RO participants, those RO participants that are eligible for the low volume opt-out in some performance years, and that there would be no impact for those RO participants that are eligible for the low volume opt-out for the entire model performance period (see section XVII.C.3.d. of this final rule with comment period).

We solicited comment on the assumptions and analysis presented throughout the regulatory impact section, section XXIV.C.6, of this final rule with comment period.

Comment: Some commenters called attention to the three percent change in the number of physician participants (measured by unique NPI) that will receive the APM incentive payment under the Quality Payment Program for 2022 as CMS now projects 80 percent (down from 83 percent as projected in the Specialty Care Models final rule) of physician participants will receive the APM incentive payment. These commenters note that it will be devastating for those practices unable to attain Advanced APM status as many of them will be left with fewer resources.

Response: Please see Table 92 in this final rule with comment period. It is important to note that the PGP figures in Table 92 encompass entities defined under the RO Model as a Medicare-enrolled PGPs and includes freestanding radiation therapy centers, as both are paid through the MPFS. The HOPD figures in Table 92 encompass entities defined under the RO Model as HOPDs, which are paid through the OPPS. On average, we estimate that PGPs (including freestanding radiation therapy centers) furnishing included RT services under the RO Model will see an increase in payment relative to those same entities outside of the RO Model, whereas HOPDs furnishing included RT services under the RO Model are expected, on average, to see a decrease in payment relative to their counterparts outside of the RO Model.

As seen in Table 92, we project that for PGP participants, the RO Model discounts will be offset in the first year of the model performance period by use of blended PFS and OPPS trend update factors. By 2024 RO participants that are PGPs (including freestanding radiation therapy centers) are expected to see an average increase in payment rates on average of approximately 6.3 percent. Over the lifetime of the RO Model we expect about 95 percent of RO participants that are PGPs (including freestanding radiation therapy centers) to see increases in payment relative to traditional FFS. This is due to the OPPS receiving projected updates of 2.3 percent on average for the 2019–2026 period, the PFS being legislated to receive effectively no conversion factor update on net for these years, and the use of blended updates redistributing a large portion of work RVU revisions finalized in the CY 2021 PFS PPS final rule onto HOPDs. Also, we assume limited dollars under the APM incentive payment, because it is limited to one year.

Comment: Some commenters stated that CMS' regulatory impact analysis significantly underestimates the cost of collecting and reporting quality measures and CDEs, and that CMS does not adequately recognize the time and resources necessary to comply with the reporting requirements. One commenter stated hearing that one hospital system that spanned eight regions within the health system uses an existing radiation oncology EHR system, but only a couple of the regions are using it to document care. Those systems that are using the EHR system to document care need to implement various software product upgrades to support the higher level CEHRT requirements. The commenter reported a cost of an estimated $1.74 million for all eight regions to be compliant with Model requirements, and that this cost does not include the cost associated with staff time or the ramp up time necessary to train and operationalize these new systems. This same commenter reported that a large academic medical center with OCM experience, has reported to them that

the cost of compliance is three- to four-times the anticipated cost of the 2-percent withhold.

Response: We thank these commenters for explaining their concerns. We continue to expect the burden costs per small entity associated with quality measure reporting to be small because three of the four measures for the RO Model are already in use in other CMS programs; and compliance with the Treatment Summary Communication (the measure not currently in use) is a best practice that should already be the standard of care across PGPs and HOPDs. In the Medicare Specialty Models final rule (85 FR 61360), we explain that the use of EHR technology is not included in the regulatory impact analysis as part of the cost of the Model, because an entity's EHR has many uses within the clinical setting and is not solely used for RO Model measures reporting. Please note that we will be monitoring burden on RO participants throughout the model performance period.

Comment: Many commenters stated that CMS estimates do not appropriately account for the proposed conversion factor and relative value units (RVUs) under the CY 2022 Medicare Physician Fee Schedule (MPFS) proposed rule. Many commenters believed CMS has failed to account for the continued decline in MPFS rates that factor into the RO Model payment methodology as part of the trend factor calculation. These commenters stated that under the CY 2022 MPFS proposed rule, CMS is proposing cuts of 8.75 percent across all radiation oncology services, due to the proposed change in Clinical Labor Pricing Inputs and the expiration of the Consolidated Appropriations Act (CCA), which equates to a cut of 3.75 percent to the conversion factor. These commenters stated that the MPFS proposals in the CY 2022 MPFS proposed rule affect the RO Model due to its trend factors, which use the MPFS and the OPPS payment rates to update the national base rate amounts each year. These commenters argued that CMS is understating the impact of the cuts with the comparison to 2020, not 2021. One commenter noted that CMS's impact estimates for PGPs, in particular, is deceiving, given significant reductions in MPFS payments proposed by CMS. Many commenters also noted their belief that the proposed payment reductions under the MPFS, when combined with the Model's withholds and discount factor, will be unsustainable for RT providers and RT suppliers under the Model and likely result in access issues for beneficiaries. They argued that these reductions have the potential to put many practices at financial risk, particularly those with thin operating margins.

One commenter argued that CMS inappropriately included the incentive payments provided to Qualified Participant (QP) status in its budgetary calculations for the RO Model. This commenter cites the Act at section 1833(z)(1)(C), which states: ''Payments under this subsection shall not be taken into account for purposes of determining actual expenditures under an alternative payment model and for purposes of determining or rebasing any benchmarks used under the alternative payment model.'' In Table 78 of the CY 2022 OPPS/ASC proposed rule (86 FR 42351), CMS has included the incentive payments for RO Model QPs in its calculations of net savings attributable to the Model. The commenter stated that the purpose of the QP incentive payments is to help support APM participants as they transition from the traditional fee-for-service system to payment under APMs, and that these incentive payments should not be considered costs attributable to the RO Model.

A couple of commenters stated that CMS estimates do not appropriately account for sequestration. Finally, a commenter urges CMS to release the assumptions upon which their actuaries rest their analysis, as well as the analysis itself, so that stakeholders can understand how they arrived at their calculations.

Response: We direct readers to section XVIII.C.5.h of this final rule with comment period where we address comments specific to the impact of the discount factors on payment and to section XVIII.C.5.d of this final rule with comment period where we address comments concerning the trend factor methodology with its incorporation of MPFS and OPPS rates as part of an annual update for the PC and TC of each disease site. We do, however, acknowledge that the RO estimates could change due to CY 2022 or subsequent MPFS policies, in addition to a variety of other factors. It is important to note that the figures listed in Table 92 should be interpreted as an overall comparison between those participating in the RO Model to those outside of it during the 5-year model performance period, all else equal. This analysis therefore excludes impacts due to other CMS policy changes. The figures listed in Table 92 are averages and should not be interpreted as the reduction or increase in current payment that an individual PGP (including freestanding radiation therapy centers) or an individual HOPD receives.

As for the comment concerning the inclusion of APM incentive payments in the RO Model savings estimates, the APM incentive payment will not be included in accounting of expenditures during the Model's reconciliation for RO participants. Finally, actuarial assumptions used to calculate the financial impacts of the RO Model are included in this section of this final rule with comment period. We have added several clarifying statements throughout this section to facilitate understanding of the RO Model's financial impacts and the actuarial assumptions on which these impacts are based.

7. Effects of Requirements for Hospitals To Make Public a List of Their Standard Charges

In this final rule with comment period, we are modifying 45 CFR 180.30(b) and adding new § 180.30(b)(3) to include that state forensic hospitals will be deemed to have met requirements, similar to our policy to deem Federally owned/operated hospitals as having met requirements. These state forensic hospitals and have closed populations, are not open to the general public, and the cost of care is funded by the state. This proposal will reduce the overall burden we estimated in the Hospital Price Transparency final rule by removing such hospitals from the obligation to make public standard charges in the form and manner prescribed at 45 CFR 180.

In the Hospital Price Transparency final rule, we estimated the total burden for hospitals to review and post their standard charges for the first year to be 150 hours per hospital at $11,898.60 per hospital for a total burden of 900,300 hours (150 hours × 6,002 hospitals) and total cost of $71,415,397 ($11,898.60 × 6,002 hospitals) (84 FR 65595). We estimated the total annual burden for hospitals to review and post their standard charges for subsequent years to be 46 hours per hospital at $3,610.88 per hospital for a total annual burden for subsequent years of 276,092 hours (46 hours × 6,002 hospitals) and total annual cost of $21,672,502 ($3,610.88 × 6,002 hospitals). For purposes of the changes in this rule, we assume that state forensic hospitals have complied with the Hospital Price Transparency final rule requirements in the first year of implementation (CY 2021) and are therefore basing our burden reduction estimate on the cost of implementation for subsequent years alone. In other words, because state forensic hospitals would no longer be required to make the annual updates as required under the

Hospital Price Transparency final rule, the burden reduction applies to CY 2022 and subsequent years.

We estimate that 111[609] hospitals would meet our definition of 'state forensic hospital'. To estimate the associated burden reduction for state forensic hospitals, we used the hourly cost for each labor category by referencing Bureau of Labor Statistics report on Occupational Employment and Wages (May 2020), as indicated in Table 93.[610]

TABLE 93: Occupation Titles and Wage Rates

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
General Operations Manager	11-1021	$60.45	$60.45	$120.90
Business Operations Specialist	13-1000	$37.66	$37.66	$75.32
Network and Computer System Administrator	15-1244	$43.01	$43.01	$86.02

We estimate a reduction in burden of 2 hours for a general operations manager to review and determine updates in compliance requirements, or a savings of $241.80 (2 hours * $120.90) per hospital. We estimate a total burden reduction of 222 hours (2 hours * 111 hospitals) with a total burden reduction $26,839.80 (222 hours * $120.90).

Next, we estimate a reduction in burden of 32 hours for a business operations specialist because they will no longer be required to update necessary processes and procedures and gather and compile required information, a savings of $2,410.24 (32 hours * $75.32) per hospital. We estimate a total burden reduction of 3,552 hours (32 hours * 111 hospitals) with a total burden reduction $267,536.64 (3,552 hours * $75.32).

Finally, we estimate a reduction in burden of 12 hours for network and computer system administrator because they will no longer be required to maintain the required systems to make this data publicly available, a savings of $1,032.24 (12 hours * $86.02) per hospital. We estimate a total burden reduction of 1,332 hours (12 hours * 111 hospitals) with a total burden reduction $114,578.64 (1,332 hours * $86.02).

Therefore, we believe the total annual burden reduction for the proposal in this rule, for subsequent years, to be 46 hours (2 hours + 32 hours + 12 hours) per hospital, with a savings of $3,684.28 ($241.80 + $2,410.24 + $1,032.24) per hospital. We also estimate a total annual burden reduction for subsequent years of 5,106 hours (46 hours * 111 hospitals) and a total cost of $408,955.08 ($3,684.28 * 111 hospitals), as shown in Table 94.

TABLE 94: Costs per Organization and Total Cost Figures

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)	Subsequent Year Hours
General Operations Manager	11-1021	$60.45	$60.45	$120.90	2
Business Operations Specialist	13-1000	$37.66	$37.66	$75.32	32
Network and Computer System Administrator	15-1244	$43.01	$43.01	$86.02	12
Total Hours per state forensic hospital					46
Total Reduction per state forensic hospital (Dollars)					($3,684.28)
Total hours for State forensic hospitals (hours)					5,106
Total Burden Reduction for all State forensic hospitals					($408,955.08)

We received a several comments related to the burden and costs of complying with the Hospital Price Transparency final rule. We addressed comments on these issues in the CY 2020 Hospital Price Transparency final rule's Collection of Information Requirements and Regulatory Impact Analysis (84 FR 65591–65602) and did not propose in the CY 2022 OPPS/ASC proposed rule to change any of the policies or cost analysis previously established. Accordingly we consider these comments out of scope.

Comment: Some commenters indicated that any modifications to the hospital price transparency final rule requirements could negate much of the

[609] SAMHSA. National Mental Health Services Survey (N–MHSS): 2019 Data on Mental Health Treatment Facilities. *https://www.samhsa.gov/data/sites/default/files/reports/rpt29388/2019_NMHSS/2019-NMHSS-R.pdf.*

[610] Bureau of Labor Statistics. National Occupational Employment and Wage Estimates, May 2020. Available at *https://www.bls.gov/oes/current/oes_nat.htm.*

work that has been done and would require hospitals to start over to recreate their files in a new format. Commenters stated that additional requirements would create excess administrative burden and would require a minimum of six months to implement, noting the needed time to gather data and execute the necessary IT build for reporting.

Response: In this final rule with comment period, we are finalizing the following policies: (1) Increasing the civil monetary penalty using a scaling factor; (2) deeming state forensic hospitals as having met requirements; and (3) requiring hospitals to ensure that the machine-readable file is accessible to automated searches and direct downloads. In the proposed rule, we determined that neither increasing the penalty amount nor ensuring the machine-readable file is barrier free would result in a cost burden over the amount that was estimated in the impact analysis in the Hospital Price Transparency final rule. We further estimated that the policy to deem state forensic hospitals as having met requirements would reduce hospital burden. None of the policies modify any other requirements in the Hospital Price Transparency final rule (such as changes in formatting requirements or data elements that must be displayed). We therefore disagree with commenters that the modifications made in this final rule will ''negate'' work already done by hospitals to come into compliance or that such policy modifications would cause a hospital to spend 6 months to gather and display information or that such policy modifications would ''require hospitals to start over to recreate their files in a new format.'' Additionally, we have assessed the final policies in this final rule with comment period to result in an overall burden reduction and therefore disagree that the policies we are finalizing in this rule will ''create excess administrative burden.''

Comment: Some commenters recommended that in the spirit of setting hospitals up for success, CMS should provide sufficient notification when making any changes to the reporting requirements and allow hospitals adequate time for feedback related to costs of implementation. A few commenters suggested that CMS collect post-implementation cost estimates and publish them on a public facing website or otherwise take them into account in future impact analyses.

Response: We believe that the rulemaking process provides sufficient notification of proposed changes and allows adequate time for stakeholders to submit substantive comments related to costs of implementation. We appreciate the additional suggestions related to development of future impact analyses, however, we believe that such a requirement (if finalized in future rulemaking) would impose an unnecessary burden on stakeholders and CMS.

D. Regulatory Review Costs

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 a rule, we assumed that the number of commenters on this final rule with comment period (1,349) will be the number of reviewers of this final rule with comment period. We acknowledge that this assumption may understate or overstate the costs of reviewing proposed rule. It is possible that not all commenters will review the proposed rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. Nonetheless, we believe that the number of commenters on the CY 2022 OPPS/ASC proposed rule is a fair estimate of the number of reviewers of the final rule. We welcome any comments on the approach in estimating the number of entities that will review the final rule. We also recognize that different types of entities are, in many cases, affected by mutually exclusive sections of the proposed rule and the final rule with comment period, and, therefore, for the purposes of our estimate, we assumed that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the 2020 BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rule is $114.24 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 will take approximately 8 hours for the staff to review half of final rule. For each facility that reviewed the proposed rule, the estimated cost is $913.92 (8 hours × $114.24). Therefore, we estimated that the total cost of reviewing the final rule is $17,057,493 ($913.92 × 18,664 reviewers on the CY 2022 proposed rule).

E. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, many hospitals are considered small businesses either by the Small Business Administration's size standards with total revenues of $41.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $16.5 million or less in any single year. For details, we refer readers to the Small Business Administration's ''Table of Size Standards'' at *http://www.sba.gov/content/table-small-business-size-standards*. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this final rule with comment period. As a result, the Secretary has determined that this final rule with comment period will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this final rule with comment period would increase payments to small rural hospitals by approximately 2 percent. Therefore, it should not have a significant impact on approximately 583 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the services that they provide as well as the payment policies and/or payment systems that may apply to them. Therefore, the most applicable estimated impact may be based on the specialty, provider type, or payment system.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis. We note that the policies established in this final rule with comment period apply more broadly to OPPS providers and do not specifically focus on small rural hospitals. As a result, the impact on those providers may depend more significantly on their case mix of services provided, since the broader impact on the hospital category is more dependent on the OPD update factor, as indicated in the impact table.

F. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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 2021, that threshold level is currently approximately $158 million. This final rule with comment period does not mandate any requirements for state, local, or tribal governments, or for the private sector.

G. Conclusion

The changes we are making in this final rule with comment period will affect all classes of hospitals paid under the OPPS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS will experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2022. Table 84 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 1.6 percent increase in payments for all services paid under the OPPS in CY 2022, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier state wage index adjustment, estimated payment for outliers, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2022.

The updates we are making to the ASC payment system for CY 2022 would affect each of the approximately 5,600 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 85 demonstrates the estimated distributional impact among ASC surgical specialties of the productivity-adjusted hospital market basket update factor of 2.0 percent for CY 2022.

H. Federalism Analysis

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 costs on state and local governments, preempts state law, or otherwise has federalism implications. We have examined the OPPS and ASC provisions included in this final rule with comment period in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on state, local or tribal governments, preempt state law, or otherwise have a federalism implication. As reflected in Table 84 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including state and local governmental hospitals) will increase by 1.7 percent under this final rule with comment period. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this final rule with comment period, in conjunction with the remainder of this document, demonstrate that this final rule with comment period is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This final rule with comment period will affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant. However, as noted in section XXIV.E., this final rule should not have a significant effect on small rural hospitals.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October, 28, 2021.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

45 CFR Part 180

Hospitals, Reporting and recordkeeping requirements.

Centers for Medicare & Medicaid Services

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 412.3 is amended by revising paragraph (d)(2)(i) to read as follows:

§ 412.3 Admissions.

* * * * *

(d) * * *

(2) * * *

(i) For those services and procedures removed on or after January 1, 2020, the exemption in this paragraph (d)(2) will last for 2 years from the date of such removal.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 3. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 4. Section 416.164 is amended by revising paragraphs (a)(4) and (b)(6) to read as follows:

§ 416.164 Scope of ASC services.

(a) * * *

(4) Drugs and biologicals for which separate payment is not allowed under the hospital outpatient prospective payment system (OPPS), with the exception of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174;

* * * * *

(b) * * *

(6) Non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174.

* * * * *

■ 5. Section 416.166 is revised to read as follows:

§ 416.166 Covered surgical procedures.

(a) *Covered surgical procedures.* Effective for services furnished on or after January 1, 2022, covered surgical procedures are those procedures that meet the general standards described in paragraph (b) of this section (whether commonly furnished in an ASC or a physician's office) and are not excluded under paragraph (c) of this section.

(b) *General standards.* Subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

(c) *General exclusions.* Notwithstanding paragraph (b) of this section, covered surgical procedures do not include those surgical procedures that —

(1) Generally result in extensive blood loss;

(2) Require major or prolonged invasion of body cavities;

(3) Directly involve major blood vessels;

(4) Are generally emergent or life-threatening in nature;

(5) Commonly require systemic thrombolytic therapy;

(6) Are designated as requiring inpatient care under § 419.22(n) of this chapter;

(7) Can only be reported using a CPT unlisted surgical procedure code; or

(8) Are otherwise excluded under § 411.15 of this chapter.

(d) *Additions to the list of ASC covered surgical procedures.* Surgical procedures are added to the list of ASC covered surgical procedures as follows:

(1) *Nominations.* On or after January 1, 2023, an external party may nominate a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year.

(2) *Inclusion in rulemaking.* If CMS identifies a surgical procedure that meets the requirements at paragraph (a) of this section, including a surgical procedure nominated under paragraph (d)(1) of this section, it will propose to add the surgical procedure to the list of ASC covered surgical procedures in the next available annual rulemaking.

■ 6. Section 416.171 is amended by revising paragraphs (b)(1) and (4) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) * * *

(1) Covered ancillary services specified in § 416.164(b), with the exception of radiology services and certain diagnostic tests as provided in § 416.164(b)(5) and non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174.

* * * * *

(4) Notwithstanding paragraph (b)(2) of this section, procedures assigned to Low Volume APCs where the otherwise applicable payment rate calculated based on the standard methodology for such procedures described in paragraph (b) of this section would exceed the payment rate for the equivalent service set under the payment system established under part 419 of this chapter, for which the payment rate will be set at an amount equal to the amount under that payment system.

* * * * *

■ 7. Section 416.174 is added to reads as follows:

§ 416.174 Payment for non-opioid pain management drugs and biologicals that function as supplies in surgical procedures.

(a) *Eligibility for separate payment for non-opioid pain management drugs and biologicals.* Beginning on or after January 1, 2022, a non-opioid pain management drug or biological that functions as a surgical supply is eligible for separate payment if CMS determines it meets the following requirements:

(1) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j), or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product has an FDA approved indication for pain management or analgesia.

(2) The per-day cost of the drug or biological must exceed the OPPS drug packaging threshold set annually through notice and comment rulemaking.

(b) [Reserved]

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 8. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 9. Section 419.22 is amended by revising paragraph (n) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(n) Services and procedures that the Secretary designates as requiring inpatient care.

* * * * *

■ 10. Section 419.23 is added to read as follows:

§ 419.23 Removal of services and procedures from the Inpatient Only List.

(a) *Inpatient Only List.* CMS maintains a list of services and procedures that the Secretary designates as requiring inpatient care under § 419.22(n) that are not paid under the hospital outpatient prospective payment system. This list is referred to as the Inpatient Only List.

(b) *Removals from the Inpatient Only List.* CMS assesses annually whether a service or procedure on the Inpatient Only List described in paragraph (a) of this section should be removed from the list by determining whether the service or procedure meets at least one of the following criteria:

(1) Most outpatient departments are equipped to provide the service or procedure to the Medicare population.

(2) The simplest service or procedure described by the code may be performed in most outpatient departments.

(3) The service or procedure is related to codes that CMS has already removed from the Inpatient Only List described in paragraph (a) of this section.

(4) CMS determines that the service or procedure is being performed in numerous hospitals on an outpatient basis.

(5) CMS determines that the service or procedure can be appropriately and safely performed in an ambulatory surgical center, and is specified as a covered ambulatory surgical procedure under § 416.166 of this chapter, or CMS has proposed to specify it as a covered ambulatory surgical procedure under § 416.166 of this chapter.

■ 11. Section 419.46 is amended by revising paragraphs (f)(1) and (3) to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(f) * * *

(1) Upon written request by CMS or its contractor, a hospital must submit to

CMS supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 30 days of the date identified on the written request, in the form and manner specified in the written request.

* * * * *

(3) CMS will select a random sample of 450 hospitals for validation purposes, and will select an additional 50 hospitals for validation purposes based on the following criteria:

(i) The hospital fails the validation requirement that applies to the previous year's payment determination; or

(ii) The hospital has an outlier value for a measure based on the data it submits. An ''outlier value'' is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score; or

(iii) Any hospital that has not been randomly selected for validation in any of the previous 3 years; or

(iv) Any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent.

* * * * *

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 12. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 13. Section 512.205 is amended by:
■ a. Adding the definition for ''Baseline period'' in alphabetical order;
■ b. Revising the definition for ''Discount factor'';
■ c. Adding definitions for ''EUC'', ''Legacy CCN'', and ''Legacy TIN'' in alphabetical order;
■ d. Revising the definition for ''Model performance period'';
■ e. Removing the definition of ''Performance year (PY)'';
■ f. Revising the definition for ''PY'' and ''Stop-loss reconciliation amount''; and
■ g. Adding definitions for ''Track One'', ''Track Two'', and ''Track Three'' in alphabetical order.

The additions and revisions read as follows:

§ 512.205 Definitions.

* * * * *

Baseline period means the three calendar year period that begins on January 1 no fewer than five years but no more than six years prior to the start of the model performance period during which episodes must initiate in order to be used in the calculation of the national base rates, each RO participant's historical experience adjustment for the PC or TC or both for the model performance period, and the RO participant's case mix adjustment for the PC or TC or both for PY1. The baseline period is January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in calendar year (CY) 2022, in which case the baseline period will be delayed based on the new model performance period (for example, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).

* * * * *

Discount factor means the percentage by which CMS reduces payment of the professional component and technical component.

(1) The reduction of payment occurs after the trend factor, the geographic adjustment, and the RO Model-specific adjustments have been applied, but before beneficiary cost-sharing and standard CMS adjustments, including sequestration, have been applied.

(2) The discount factor does not vary by cancer type.

(3) The discount factor for the professional component is 3.5 percent; the discount factor for the technical component is 4.5 percent.

* * * * *

EUC stands for ''extreme and uncontrollable circumstance'' and means a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to deliver care in accordance with the RO Model's requirements, and affects an entire region or locale.

* * * * *

Legacy CCN means a CMS certification number (CCN) that an RO participant that is a hospital outpatient department (HOPD) or its predecessor(s) previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services.

Legacy TIN means a taxpayer identification number (TIN) that an RO participant that is a PGP, or a freestanding radiation therapy center, or its predecessor(s) previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services.

* * * * *

Model performance period means the five performance years (PYs) during which RO episodes must initiate and terminate. The model performance period begins on January 1, 2022 and ends on December 31, 2026, unless the RO Model is prohibited by law from starting on January 1, 2022, in which case the model performance period begins on the earliest date permitted by law that is January 1, April 1, or July 1.

* * * * *

PY stands for performance year and means each 12-month period beginning on January 1 and ending on December 31 during the model performance period, unless the model performance period begins on a date other than January 1, in which case, the first performance year (PY1) begins on that date and ends on December 31 of the same year.

* * * * *

Stop-loss reconciliation amount means the amount set forth in § 512.285(f) owed by CMS for the loss incurred under the Model to RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services before the start of the model performance period in the CBSAs selected for participation.

* * * * *

Track One means a track for Professional participants and Dual participants that meet all RO Model requirements as specified in § 512.220, including use of CEHRT.

Track Two means a track for Professional participants and Dual participants that meet all RO Model requirements as specified in § 512.220, except for use of CEHRT.

Track Three means a track for Professional participants and Dual participants who do not meet one or more of the RO Model requirements set forth at § 512.220(a); and for all Technical participants.

* * * * *

■ 14. Section 512.210 is amended by —
■ a. Revising paragraphs (a) and (b)(5).
■ b. Adding paragraph (b)(6);
■ c. Revising paragraph (c); and
■ d. Adding paragraph (e).

The revisions and additions read as follows:

§ 512.210 RO participants and geographic areas.

(a) *RO participants.* Unless otherwise specified in paragraph (b) or (c) of this section, any Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that furnishes included RT services in a 5-digit ZIP Code linked to a CBSA selected for participation to an

RO beneficiary for an RO episode that begins and ends during the model performance period must participate in the RO Model.

(b) * * *

(5) Participates in the Pennsylvania Rural Health Model; or

(6) Participates in the Community Transformation Track of the Community Health Access and Rural Transformation (CHART) Model as a participating hospital.

(c) *Low volume opt-out.* A PGP, freestanding radiation therapy center, or HOPD that would otherwise be required to participate in the RO Model may choose to opt-out of the RO Model as follows:

(1) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 episodes in the calendar year that is two years prior to the start of PY1 across all CBSAs selected for participation, it may opt out of the RO Model for PY1.

(2) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 episodes in the calendar year that is two years prior to the start of PY2 across all CBSAs selected for participation, it may opt out of the RO Model for PY2.

(3) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 RO episodes in PY1 across all CBSAs selected for participation, and PY1 begins on January 1, it may choose to opt out of the RO Model for PY3. In the event that PY1 begins on a date other than January 1, the PGP, freestanding radiation therapy center, or HOPD may opt-out of the RO Model for PY3 if the total number of furnished episodes of the calendar year in which PY1 began and RO episodes in PY1 is fewer than 20 across all CBSAs selected for participation.

(4) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 RO episodes in PY2 across all CBSAs selected for participation, it may opt out of the RO Model for PY4.

(5) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 RO episodes in PY3 across all CBSAs selected for participation, it may opt out of the RO Model for PY5.

(6) At least 30 days prior to the start of each PY, CMS provides notice to RO participants eligible for the low volume opt-out for the upcoming PY of such eligibility. The RO participant must attest that it intends to opt out of the RO Model prior to the start of the upcoming PY.

(7) An entity is not eligible for the low-volume opt out if its current TIN or CCN, or its legacy TIN or legacy CCN, or both were used to bill Medicare for 20 or more episodes or RO episodes, as applicable, of RT services in the two years prior to the applicable PY across all CBSAs selected for participation.

* * * * *

(e) *Notice of change in TIN or CCN.* An RO participant must furnish written notice to CMS in a form and manner specified by CMS at least 90 days before the effective date of any change in TIN or CCN that is used to bill Medicare.

■ 15. Section 512.217 is amended —

■ a. By revising paragraphs (a), (b), and (c)(1);

■ b. In paragraph (c)(3)(i) by removing the word ''and'' at the end of the paragraph;

■ c. In paragraph (c)(3)(ii) by removing the period at the end of the paragraph and adding ''; and'' in its place; and

■ d. By revising paragraphs (d)(1)(i) and (d)(2)(i).

The revisions and addition read as follows:

§ 512.217 Identification of individual practitioners.

(a) *General.* Upon the start of each PY, CMS creates and provides to each RO participant that is a PGP or a freestanding radiation therapy center an individual practitioner list identifying by NPI each individual practitioner associated with the RO participant. For RO participants that begin participation in the RO Model after the start of a PY, but at least 30 days prior to the last QP determination date as specified at § 414.1325 of this chapter, CMS creates and provides an individual practitioner list to that RO participant.

(b) *Review of individual practitioner list.* Up until the last QP determination date as specified at § 414.1325 of this chapter, the RO participant must review the individual practitioner list, correct any inaccuracies in accordance with paragraph (d) of this section, and certify the list (as corrected, if applicable) in a form and manner specified by CMS and in accordance with paragraph (c) of this section. The RO participant may correct any inaccuracies in its individual practitioner list until the last QP determination date as specified at § 414.1325 of this chapter. Any Dual participant, Professional participant, or Technical participant that is a freestanding radiation therapy center and joins the RO Model after the start of a PY must review and certify its individual practitioner list by the last QP determination date as specified at § 414.1325 of this chapter.

(c) * * *

(1) Up until the last QP determination date as specified at § 414.1325 of this chapter, an individual with the authority to legally bind the RO participant must certify the accuracy, completeness, and truthfulness of the individual practitioner list to the best of his or her knowledge, information, and belief.

* * * * *

(d) * * *

(1) * * *

(i) An RO participant must notify CMS of an addition to its individual practitioner list when an eligible clinician reassigns his or her rights to receive payment from Medicare to the RO participant. The notice must be submitted in the form and manner specified by CMS up until the last QP determination date as specified at § 414.1325 of this chapter.

* * * * *

(2) * * *

(i) An RO participant must notify CMS when an individual on the RO participant's individual practitioner list ceases to be an individual practitioner up until the last QP determination date as specified at § 414.1325 of this chapter. The notice must be submitted in the form and manner specified by CMS.

* * * * *

■ 16. Section 512.220 is amended by revising paragraphs (a)(1) and (b) to read as follows:

§ 512.220 RO participant compliance with RO Model requirements.

(a) * * *

(1) An RO participant must satisfy the requirements of this section to be included in Track One under the RO Model in a particular PY. An RO participant that meets all of these RO Model requirements in a particular PY, excluding use of CEHRT, will be in Track Two for such PY. An RO participant that does not meet one or more of the RO Model requirements in paragraph (a) of this section in a particular PY will be in Track Three for such PY.

* * * * *

(b) *CEHRT.* (1) RO participants must use CEHRT, and ensure that their individual practitioners use CEHRT, in a manner sufficient to meet the applicable requirements of the Advanced APM criteria as specified at § 414.1415(a)(1)(i) of this chapter.

(2) Within 30 days of the start of PY1 and each subsequent PY, the RO participant must certify its use of CEHRT throughout such PY in a manner sufficient to meet the requirements set

forth in § 414.1415(a)(1)(i) of this chapter.

(3) An RO participant that joins the RO Model at any time during an ongoing PY must certify their use of CEHRT by the last QP determination date as specified at § 414.1325 of this chapter.

■ 17. Section 512.230 is amended by revising paragraphs (a) and (b) to read as follows:

§ 512.230 Criteria for determining cancer types.

(a) *Included cancer types.* CMS includes in the RO Model cancer types that satisfy the following criteria:

(1) The cancer type is commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines;

(2) The cancer type has one or more associated current ICD–10 codes that have demonstrated pricing stability; and

(3) The Secretary has not determined that the cancer type is not suitable for inclusion in the RO Model.

(b) *Removing cancer types.* CMS removes cancer types in the RO Model if it determines:

(1) That there is a ≥10 percent error in established national base rates; or

(2) The cancer type does not meet the criteria set forth in paragraph (a) of this section.

* * * * *

■ 18. Section 512.240 is revised to read as follows:

§ 512.240 Included modalities.

The modalities included in the RO Model are 3-dimensional conformal RT (3DCRT), intensity-modulated RT (IMRT), stereotactic radiosurgery (SRS), stereotactic body RT (SBRT), proton beam therapy (PBT), and image-guided radiation therapy (IGRT).

■ 19. Section 512.245 is amended by revising paragraph (a) to read as follows:

§ 512.245 Included RO episodes.

(a) *General.* Any RO episode that begins on or after the first day of the model performance period and ends on or before the last day of the model performance period is included in the model performance period.

* * * * *

■ 20. Section 512.250 is amended by revising (b)(1) and (2) to read as follows:

§ 512.250 Determination of national base rates.

* * * * *

(b) * * *

(1) CMS excludes from episode pricing and RO episode pricing any claim containing an RT service furnished:

(i) In Maryland, Vermont, or any of the U.S. Territories;

(ii) In the inpatient setting;

(iii) By an entity classified as an ASC, CAH, or PPS-exempt cancer hospital; or

(iv) By an HOPD participating in the Pennsylvania Rural Health Model at the time the RT service was furnished.

(2) CMS excludes the following episodes from the determination of the national base rates:

(i) Episodes that are not linked to a CBSA selected for participation in the RO Model;

(ii) Episodes that are not attributed to an RT provider or RT supplier;

(iii) Episodes that are not assigned an included cancer type; or

(iv) Episodes for which the total allowed amount for RT services listed on claims used to calculate an episode's payment amount is not greater than $0.

* * * * *

■ 21. Section 512.255 is amended by—

■ a. Revising paragraphs (c)(7), (8), and (10), (c)(12)(iv), and (c)(13); and

■ b. Adding paragraph (c)(14).

The revisions and addition read as follows:

§ 512.255 Determination of participant-specific professional episode payment and participant-specific technical episode payment amounts.

* * * * *

(c) * * *

(7) *Adjustments for RO participants with fewer than 60 episodes during the baseline period.* (i) RO participants that have fewer than 60 episodes in the baseline period do not receive a historical experience adjustment during the model performance period.

(ii) RO participants that have fewer than 60 episodes in the baseline period do not receive a case mix adjustment for PY1.

(iii) RO participants that have fewer than 60 episodes in the baseline period that continue to have fewer than 60 episodes in the rolling 3-year period used to determine the case mix adjustment for each PY and that have never received a case mix adjustment do not receive a case mix adjustment for that PY.

(iv) RO participants that have fewer than 60 episodes in the baseline period and were furnishing included RT services in the CBSAs selected for participation before the start of the model performance period are eligible to receive a stop-loss reconciliation amount, if applicable, as described in § 512.285(f).

(8) *Discount factor.* CMS reduces each episode payment by the discount factor after applying the trend factor, geographic adjustment, and case mix and historical experience adjustments to the national base rate.

* * * * *

(10) *Quality withhold.* In accordance with § 414.1415(b)(1) of this chapter, CMS withholds 2 percent from each professional episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate. RO participants may earn back this withhold, in part or in full, based on their AQS.

* * * * *

(12) * * *

(iv) In the case of incomplete episodes, the beneficiary coinsurance payment equals 20 percent of the FFS amounts that would have been paid in the absence of the RO Model for the services furnished by the RO participant that initiated the PC and the RO participant that initiated the TC (if applicable).

* * * * *

(13) *Sequestration.* In accordance with applicable law, CMS deducts a percentage from each episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, discount, withholds, and coinsurance to the national base rate.

(14) *Modifications to the participant-specific adjustments for changes in TINs or CCNs.* (i) CMS calculates the RO participant's case mix adjustments in accordance with paragraph (c)(3) of this section based on all episodes and RO episodes, as applicable, attributed to the RO participant's legacy TIN(s) or legacy CCN(s), and current TIN or CCN, during the 3-year period that determines the case mix adjustment for each PY.

(ii) CMS calculates the RO participant's historical experience adjustments in accordance with paragraph (c)(4) of this section based on all episodes attributed to the RO participant's legacy TIN(s) or legacy CCN(s), and current TIN or CCN, during the baseline period.

■ 22. Section 512.275 is amended by adding paragraph (d) to read as follows:

§ 512.275 Quality measures, clinical data, and reporting.

* * * * *

(d) *Technical participants and reporting of quality measures and clinical data elements.* Technical participants that are freestanding radiation therapy centers and also begin furnishing the professional component during the model performance period must:

(1) Notify CMS no later than 30 days after the technical participant begins

furnishing the professional component, in a form and manner specified by CMS; and

(2) Report quality measures and clinical data elements by the next submission period, as described in paragraph (c) of this section.

§ 512.280 [Amended]

■ 23. Section 512.280 is amended by removing and reserving paragraph (f)(4) to read as follows:

§ 512.280 RO Model Medicare Program Waivers

* * * * *

(f) * * *

(4) [Reserved]

* * * * *

■ 24. Section 512.285 is amended by revising paragraphs (c)(3), (c)(4)(i) and (ii), (d), and (f) introductory text to read as follows:

§ 512.285 Reconciliation process.

* * * * *

(c) * * *

(3) *Total incomplete episode amount.* For incomplete episodes initiated in the PY, CMS determines the total incomplete episode amount by calculating the difference between the following amounts:

(i) The sum of all FFS amounts that would have been paid to the RO participant in the absence of the RO Model for any included RT services furnished during such incomplete episodes, as determined by no-pay claims. CMS owes this sum to the RO participant for such incomplete episodes.

(ii) The sum of the participant-specific episode payment amounts paid to the RO participant for such incomplete episodes initiated in the PY.

(4) * * *

(i) If the sum described in paragraph (c)(3)(i) of this section is more than the sum described in paragraph (c)(3)(ii) of this section, the difference is subtracted from the total duplicate RT services amount described in paragraph (c)(2) of this section and the resulting amount is the total incorrect episode payment amount.

(ii) If the sum described in paragraph (c)(3)(i) of this section is less than the sum described in paragraph (c)(3)(ii) of this section, the difference is added to the total duplicate RT services amount described in paragraph (c)(2) of this section and the resulting amount is the total incorrect episode payment amount.

* * * * *

(d) *Quality reconciliation payment amount.* For Professional participants and Dual participants, CMS determines the quality reconciliation payment amount for each PY by multiplying the participant's AQS (as a percentage) by the total quality withhold amount for all RO episodes initiated during the PY.

* * * * *

(f) *Stop-loss reconciliation amount.* CMS determines the stop-loss reconciliation amount for RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services before the start of the model performance period in the CBSAs selected for participation by—

* * * * *

■ 25. Section 512.292 is added to read as follows:

§ 512.292 Overlap with other models tested under Section 1115A and CMS programs.

Participant-specific professional episode payments and Participant-specific technical episode payments made under the RO Model are not adjusted to reflect payments made under models being tested under 1115A of the Act or the Medicare Shared Savings Program under section 1899 of the Act.

■ 26. Section 512.294 is added to read as follows:

§ 512.294 Extreme and uncontrollable circumstances.

(a) *General.* If CMS determines that there is an EUC pursuant to paragraph (b) of this section, CMS may grant RO participants exceptions to the RO Model requirements under paragraph (c) of this section and revise the RO Model's pricing methodology under paragraphs (e) and (f) of this section.

(b) *Determination factors.* CMS determines whether there is an EUC based on the following factors:

(1) Whether the RO participants are furnishing services within a geographic area considered to be within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Social Security Act;

(2) Whether the geographic area within a county, parish, U.S. territory, or tribal government designated under the Stafford Act served as a condition precedent for the Secretary's exercise of the 1135 waiver authority, or the National Emergencies Act; or

(3) Whether a state of emergency has been declared in the geographic area.

(c) *Modified requirements.* CMS may grant RO Participants exceptions to the following RO Model requirements:

(1) *Reporting requirements.* CMS may delay or exempt RO participants from one or more of the RO Model's quality measure or clinical data element reporting requirements if an EUC impacts the RO participants' ability to comply with quality measure or clinical data element reporting requirements.

(2) *Other requirements.* CMS may issue a notice on the RO Model website that may waive compliance with or modify the following RO Model requirements:

(i) The requirement set forth at § 512.220(a)(2)(vii) that RO participants provide Peer Review (audit and feedback on treatment plans).

(ii) The requirement set forth at § 512.220(a)(3) that RO participants actively engage with an AHRQ-listed patient safety organization (PSO).

(d) *Model performance period.* If CMS determines that the EUC affects the United States and if CMS determines that the EUC would impact RO participants' ability to implement the requirements of the RO Model prior to the start of the model performance period, CMS may amend the model performance period.

(e) *Trend factor.* If CMS determines that the EUC affects the entire United States, and if CMS determines that as a result of the EUC, the trend factor (specific to the PC, TC, or both for an included cancer type) for the upcoming PY has increased or decreased by more than 10 percent compared to the corresponding trend factor of the previous CY when FFS payment rates are held constant with the previous CY, CMS may modify the trend factor calculation for the PC, TC, or both the PC and TC of an included cancer type in a manner that ensures the trend factor is consistent with the average utilization from the previous CY.

(f) *Quality withhold.* In response to a national, regional, or local event, CMS may adjust the quality withhold by choosing to repay the quality withhold during the next reconciliation and award all possible points in the subsequent AQS calculation amount or to not apply the quality withhold to RO Model payments during the EUC if CMS removes the quality measure and clinical data element reporting requirements pursuant to paragraph (c)(1) of this section.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 180 as set forth below:

PART 180—HOSPITAL PRICE TRANSPARENCY

■ 27. The authority citation for part 180 continues to read as follows:

Authority: 42 U.S.C. 300gg–18, 42 U.S.C. 1302.

■ 28. Section 180.20 is amended by adding a definition for ''State forensic hospital'' in alphabetical order to read as follows:

§ 180.20 Definitions.

* * * * *

State forensic hospital means a public psychiatric hospital that provides treatment for individuals who are in the custody of penal authorities.

* * * * *

■ 29. Section 180.30 is amended—

■ a. In paragraph (b) introductory text by removing the phrase ''Federally owned or operated hospitals'' and adding in its place the phrase ''Federal and State hospitals''; and

■ b. By adding paragraph (b)(3).

The addition reads as follows:

§ 180.30 Applicability.

* * * * *

(b) * * *

(3) State forensic hospitals that provide treatment exclusively to individuals who are in the custody of penal authorities.

* * * * *

■ 30. Section 180.50 is amended—

■ a. In paragraph (d)(3)(ii) by removing the word ''and'' at the end of the paragraph;

■ b. In paragraph (d)(3)(iii) by removing the period at the end of the paragraph and adding ''; and'' in its place; and

■ c. By adding paragraph (d)(3)(iv).

The addition reads as follows:

§ 180.50 Requirements for making public hospital standard charges for all items and services.

* * * * *

(d) * * *

(3) * * *

(iv) To automated searches and direct file downloads through a link posted on a publicly available website.

* * * * *

■ 31. Section 180.90 is amended by revising paragraph (c)(2) to read as follows:

§ 180.90 Civil monetary penalties.

* * * * *

(c) * * *

(2) CMS determines the daily dollar amount for a civil monetary penalty for which a hospital may be subject as follows:

(i) For each day during Calendar Year 2021 that a hospital is determined by CMS to be out of compliance, the maximum daily dollar amount for a civil monetary penalty to which the hospital may be subject is $300. Even if the hospital is in violation of multiple discrete requirements of this part, the maximum total sum that a single hospital may be assessed per day is $300.

(ii) Beginning January 1, 2022, for each day a hospital is determined by CMS to be out of compliance:

(A) For a hospital with a number of beds equal to or less than 30, the maximum daily dollar civil monetary penalty amount to which it may be subject is $300, even if the hospital is in violation of multiple discrete requirements of this part.

(B) For a hospital with at least 31 and up to and including 550 beds, the maximum daily dollar civil monetary penalty amount to which it may be subject is the number of beds times $10, even if the hospital is in violation of multiple discrete requirements of this part.

(C) For a hospital with a number of beds greater than 550, the maximum daily dollar civil monetary penalty amount to which it may be subject is $5,500, even if the hospital is in violation of multiple discrete requirements of this part.

(D)(*1*) CMS will use the most recently available, finalized Medicare hospital cost report to determine the number of beds for a Medicare-enrolled hospital, for purposes of determining the maximum daily dollar civil monetary penalty amount under paragraph (c)(2) of this section.

(*2*) If the number of beds for the hospital cannot be determined according to paragraph (c)(2)(ii)(D)(*1*) of this section, CMS will request that the hospital provide documentation of its number of beds, in a form and manner and by the deadline prescribed by CMS in a written notice provided to the hospital. Should the hospital fail to provide CMS with this documentation in the prescribed form and manner, and by the specified deadline, CMS will impose on the hospital the maximum daily dollar civil monetary penalty amount according to paragraph (c)(2)(ii)(C) of this section.

* * * * *

Dated: October 29, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–24011 Filed 11–2–21; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 86 Tuesday,

No. 218 November 16, 2021

Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Threatened Species Status With Section 4(d) Rule for Atlantic Pigtoe and Designation of Critical Habitat; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2018–0046; FF09E21000 FXES1111090FEDR 223]

RIN 1018–BD12

Endangered and Threatened Wildlife and Plants; Threatened Species Status With Section 4(d) Rule for Atlantic Pigtoe and Designation of Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), list the Atlantic pigtoe, (*Fusconaia masoni*), a freshwater mussel species from Virginia and North Carolina, as a threatened species with a rule issued under section 4(d) of the Endangered Species Act of 1973 (Act), as amended. We also designate critical habitat for the species under the Act. In total, approximately 563 river miles (906 river kilometers) fall within 17 units of critical habitat in Bath, Botetourt, Brunswick, Craig, Dinwiddie, Greensville, Halifax, Lunenburg, Mecklenburg, Nottoway, Pittsylvania, and Sussex Counties, Virginia, and in Durham, Edgecombe, Franklin, Granville, Halifax, Johnston, Montgomery, Nash, Orange, Person, Pitt, Randolph, Rockingham, Vance, Wake, Warren, and Wilson Counties, North Carolina. This rule extends the Act's protections to the species and its designated critical habitat.

DATES: This rule is effective December 16, 2021.

ADDRESSES: This final rule is available on the internet at *http://www.regulations.gov* under Docket No. FWS–R4–ES–2018–0046. Comments and materials we received, as well as supporting documentation we used in preparing this rule, are available for public inspection at *http://www.regulations.gov.*

The coordinates or plot points from which the maps are generated are included in the decision file for this critical habitat designation and are available at *http://www.regulations.gov* at Docket No. FWS–R4–ES–2018–0046 and the shapefiles for the critical habitat designation are available on the Service's Environmental Conservation Online System (ECOS) website at *http://ecos.fws.gov/ecp/species/5164.* Any additional tools or supporting information that we developed for this critical habitat designation will also be available at the Service's website set out above or at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Pete Benjamin, Field Supervisor, U.S. Fish and Wildlife Service, Raleigh Ecological Services Field Office, 551F Pylon Drive, Raleigh, NC 27606; telephone 919–816–6408. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, if we determine that a species is an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal to list the species in the **Federal Register** and make a determination on our proposal within one year. If there is substantial disagreement regarding the sufficiency and accuracy of the available data relevant to the proposed listing, we may extend the final determination for not more than six months. To the maximum extent prudent and determinable, we must designate critical habitat for any species that we determine to be an endangered or threatened species under the Act. When we list a species as a threatened species, we issue such regulations as deemed necessary and advisable to provide for the conservation of such species. In addition, we may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1) of the Act for endangered species. Listing a species as an endangered or threatened species, designation of critical habitat, and protection of threatened species can only be completed by issuing a rule.

What this document does. This rule finalizes the listing of the Atlantic pigtoe (*Fusconaia masoni*) as a threatened species with a rule issued under section 4(d) of the Act (a ''4(d) rule'') and designates critical habitat in 17 units totaling approximately 563 river miles (906 river kilometers (km)) within portions of 12 counties in Virginia and 17 counties in North Carolina.

The basis for our action. Under section 4(a)(1) of the Act, we may determine that a species is an endangered or threatened species based on any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that habitat degradation (Factor A), resulting from the cumulative impacts of land use change and associated watershed-level effects on water quality, water quantity, habitat connectivity, and instream habitat suitability, poses the largest risk to the future viability of the Atlantic pigtoe. This stressor primarily consists of habitat changes: The buildup of fine sediments, the loss of flowing water, instream habitat fragmentation, and impairment of water quality, and it is exacerbated by the effects of climate change (Factor E). Further, the existing regulatory mechanisms are not adequate to reduce these threats so that the species would not warrant listing (Factor D).

Section 4(a)(3) of the Act requires the Secretary of the Interior (Secretary) to designate critical habitat concurrent with listing to the maximum extent prudent and determinable. Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat.

Economic analysis. In accordance with section 4(b)(2) of the Act, we prepared an economic analysis of the impacts of designating critical habitat. On October 11, 2018, we published an announcement of, and solicited public comments on, the draft economic analysis (83 FR 51570). The September 22, 2020, revisions to proposed critical habitat (85 FR 59487) did not affect the economic analysis because the impacts on the counties with new proposed units were already factored into the original analysis. We received no comments on the draft economic analysis and adopted the draft economic analysis as final.

Peer review and public comment. Prior to development of our October 11, 2018, proposed rule, we received peer reviews of the Species Status

Assessment (SSA) report from two experts, which informed our assessment that we used for this rulemaking. Information we received from peer review is incorporated into this final rule. We also considered all comments and information we received from the public during two public comment periods.

Previous Federal Actions

Please refer to the proposed listing rule for the Atlantic pigtoe (83 FR 51570) for a detailed description of previous Federal actions concerning this species. We published a proposed listing, 4(d) rule, and critical habitat designation for the Atlantic pigtoe on October 11, 2018 (83 FR 51570); we accepted public comments on the proposed rule for 60 days, ending December 10, 2018. Based on information we received during the public comment period, on September 22, 2020, we proposed a revised 4(d) rule and critical habitat designation for the Atlantic pigtoe (85 FR 59487); we accepted public comments on the proposed revisions as well as the October 11, 2018, proposed rule for 30 days, ending October 22, 2020. Please refer to the October 11, 2018, and September 22, 2020, documents for detailed descriptions of other previous Federal actions concerning this species.

Supporting Documents

An SSA team prepared an SSA report for the Atlantic pigtoe. The SSA team was composed of Service biologists, in consultation with other species experts. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the Atlantic pigtoe, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species. The SSA report and other materials relating to this rule can be found *at http://www.regulations.gov* under Docket No. FWS–R4–ES–2018–0046.

Summary of Changes From the Proposed Rule

This final rule incorporates several changes to our proposed rule (83 FR 51570; October 11, 2018) based on the comments we received during that proposal's 60-day comment period as well as during the reopened public comment (see 85 FR 59487; September 22, 2020), which are summarized below under Summary of Comments and Recommendations. Minor, nonsubstantive changes and corrections were made throughout this rule in response to comments. Based on these comments, we also incorporated as appropriate new information into our SSA report, including updated survey information. The information we received during both public comment periods did not change our determination that the Atlantic pigtoe is a threatened species.

We received substantive comments on the proposed 4(d) rule and critical habitat designation, and we made changes to both of these as a result. We made changes to the 4(d) rule exceptions to the incidental take prohibitions as follows:

- For incidental take resulting from species restoration efforts by State wildlife agencies, we now include monitoring, which is necessary to determine the success of captive propagation and stocking efforts;
- For channel restoration projects, we remove erroneous mention of second- to third-order streams, and we add language to require surveys for and relocation of Atlantic pigtoe observed prior to commencement of restoration action;
- For bank stabilization projects, we add a requirement that appropriate ''native'' vegetation, including woody and herbaceous species appropriate for the region and habitat, be used for stabilization; and
- For forestry-related actions, we use alternative language provided by NCFS and VDOF (see *(13) Comment* under Summary of Comments and Recommendations, below).

We have also changed the way in which the provisions of the 4(d) rule will appear at 50 CFR 17.45(a). We no longer generally refer to the 50 CFR 17.31 prohibitions and exceptions to those prohibitions, but instead specify the applicable prohibitions in the 4(d) rule. In addition, for clarity and readability, we present separate lists for the general exceptions to the prohibitions and the exceptions from prohibitions for specific types of incidental take. However, these changes are simply formatting changes and do not affect the substance of the 4(d) rule.

For the critical habitat designation, we removed proposed Unit 3 (Middle James River) based on comments received from the VADWR (see *(9) Comment* under Summary of Comments and Recommendations, below). This removal changes the numbering of all following units (Units 4 through 18 become Units 3 through 17); therefore, revisions to the proposed critical habitat designation described in the September 22, 2020, document (85 FR 59487) differ slightly, but only by unit numbering, than as presented in this rule. We added two critical habitat units (Sappony Creek Unit (now Unit 3) and Little Grassy Creek Unit (now Unit 8)) and modified four units (Nottoway River Subbasin (now Unit 4), Dan River (now Unit 6), Upper/Middle Tar River Subbasin (now Unit 9), Sandy/Swift Creek (now Unit 10)) of the critical habitat designation for Atlantic pigtoe, for a total critical habitat designation of 563 river miles (906 river kilometers), an increase of 21 river miles (34 river kilometers) from the October 11, 2018, proposed designation.

We also added information about regulatory mechanisms to Factors Influencing Atlantic Pigtoe Viability (below), including information about state endangered species laws, state and federal stream protections, and state and federal water quality programs.

Summary of Comments and Recommendations

In the October 11, 2018, and September 22, 2020, proposed rules, we requested that all interested parties submit written comments. We also contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposed rules. Newspaper notices inviting general public comment were published in the USA Today legal notice section on October 25, 2018, and October 1, 2020. Although we invited requests for a public hearing in both proposed rules, we did not receive any requests for a public hearing. All substantive information received during both comment periods has either been incorporated directly into this final determination or is addressed below. For topics we received comments on during both comment periods, we specify whether the comments were received as part of the initial comment period (October 11–December 10, 2018) or the reopened comment period (September 22–October 22, 2020).

Peer Reviewer Comments

In accordance with our peer review policy published on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we solicited expert opinion regarding the SSA report from six knowledgeable individuals with scientific expertise that included familiarity with Atlantic pigtoe and its habitat, biological needs, and threats. We received responses from two of those individuals. We reviewed all comments we received from the peer reviewers for substantive issues and new information regarding the information contained in the SSA report. The peer reviewers generally

concurred with our methods and conclusions, and provided additional information, clarifications, and suggestions to improve the SSA report. Peer reviewer comments are addressed in the following summary and were incorporated into the SSA report as appropriate.

(1) Comment: One peer reviewer noted that redundancy calculations provided in the Summary Table of the SSA report were confusing and asked us to clarify changes in redundancy for current condition.

Our Response: Because redundancy relates to the number and distribution of populations, we used the number of occupied watersheds, or HUCs (Hydrologic Unit Codes), to clarify changes in redundancy, as summarized in Table ES–1 of the SSA report. For current condition, there has been a 60 percent reduction in redundancy across the species' historical range (*i.e.,* 31 out of 81 HUCs are now currently occupied; 31/81 = 0.4, which equates to a reduction of 0.6 or 60 percent).

State Agency Comments

We received comments from six State agencies: The North Carolina Wildlife Resources Commission (NCWRC), the Georgia Department of Natural Resources (GADNR), the Virginia Department of Wildlife Resources (VADWR), the South Carolina Department of Natural Resources (SCDNR), the North Carolina Forest Service (NCFS), and the Virginia Department of Forestry (VDOF). Because we received several comments from both NCFS and VDOF and the public regarding forestry considerations, we address most NCFS and VDOF comments in the *Public Comments* section, below.

(2) Comment: The GADNR recommended we use an occupancy model analysis to inform our population factors.

Our Response: Occupancy modeling relies on multiple visits to the same site over time, thus allowing for an estimation of detection. At the time of SSA analysis (2015–2016), the available rangewide data were not conducive for use with occupancy models. We did not receive additional occupancy data during the public comment periods that would allow us to conduct an occupancy model analysis.

(3) Comment: The NCWRC noted that it has not been able to do intensive surveys for Atlantic pigtoe in portions of the Cape Fear River Basin. It suggested that the Optimistic Scenario consider the potential to find additional populations in the Piedmont to reflect that the species exists in areas where surveys have not been updated and habitat conditions have not changed.

Our Response: The narrative portion of the SSA report acknowledges the possibility of finding new locations for the species. However, those findings are not reflected in the Scenario table because the potential future abundances are not known and therefore cannot be incorporated into future condition categorization.

(4) Comment: The NCWRC commented that several areas within the known range of the Atlantic pigtoe have not been surveyed sufficiently since 2005 to conclude that the species is not present.

Our Response: We recognize that detection is imperfect; therefore, we involved NCWRC biologists in the development of the SSA report and sought their input into the decision to use 2005 as the earliest date for ''current.'' This year was selected based on the perceived adequacy of survey effort from 2005–2015 for justifying current species presence/absence conclusions. Ultimately, we relied on data provided by each state's agency biologists to develop the distribution and abundance heat maps contained in Appendix B of the SSA report.

(5) Comment: The NCWRC noted that many of the critical habitat reaches lack definable limits that can be precisely described and recommended that critical habitat units start and end at distinct locations, such as tributary confluences or road crossings.

Our Response: For the purposes of this rule, critical habitat reaches are defined based on Natural Heritage species ''element occurrences.'' An element occurrence is an area of land and/or water in which a species or ecological community is present. Since these comprise the best available scientific information, we used them for unit boundaries rather than relying on a tributary confluence or road crossing. Both coordinates or plot points from which the maps are generated and shapefiles are available (see **ADDRESSES**, above) to help users precisely identify limits on a map.

(6) Comment: The NCWRC recommended the 4(d) rule be clarified to state that provisions of sections 7 and 9(a)(1) of the Act will not apply to those areas where Atlantic pigtoe are stocked by NCWRC or Service biologists into unoccupied habitat. This clarification will allow biologists to stock Atlantic pigtoe in suitable yet currently unoccupied habitat within the species' historical range without these restored populations being subject to the provisions of sections 7 and 9(a)(1) of the Act.

Our Response: We recognize the special and unique relationship with our State natural resource agency partners in contributing to conservation of listed species. Therefore, under the final 4(d) rule, any qualified employee or agent of a State conservation agency, that is a party to a cooperative agreement with the Service in accordance with section 6(c) of the Act, and who is designated by his or her agency for such purposes, will be able to conduct activities designed to conserve Atlantic pigtoe that may result in otherwise prohibited take without additional authorization.

Nothing in this final 4(d) rule changes in any way the consultation requirements under section 7 of the Act. However, interagency cooperation may be further streamlined through planned programmatic consultations for the species between Federal agencies and the Service, where appropriate.

(7) Comment: The NCWRC provided recommendations, with supporting data, to revise the 4(d) rule language by adding (a) monitoring to the species restoration exception for incidental take; (b) language to the channel restoration exception for incidental take that requires surveys for and relocation of Atlantic pigtoe observed prior to commencement of restoration action; and (c) language to the incidental take exception resulting from bank stabilization projects to add a requirement that appropriate ''native'' vegetation, including woody and herbaceous species appropriate for the region and habitat, be used for stabilization.

Our Response: The suggested revisions are important considerations to include in the exceptions outlined and provide for the conservation of the Atlantic pigtoe, therefore we made the suggested revisions to the 4(d) rule.

(8) Comment: The NCWRC provided recommendations, with supporting data, to revise several critical habitat units, truncating two units (*i.e.,* removing 3.8 river miles from Upper/Middle Tar River Subbasin and 8.2 river miles from Sandy/Swift Creek), adding occupied habitat to two units (10 river miles to Upper/Middle Tar River Subbasin and 7 river miles to Dan River), and creating a new unit (Little Grassy Creek). During the reopened comment period, the VADWR suggested the removal of the Middle James River critical habitat unit, noting that the last detection of living Atlantic pigtoe in that reach was in the late 1960s.

Our Response: As announced in our reopening of the rule, we reviewed this new information received from State agencies, in conjunction with all prior

data. In doing so, we noted an accidental omission error during our mapping of critical habitat that resulted in the omission of a 2011 observation of Atlantic pigtoe in Sappony Creek. Based on the new information, we made several revisions to the proposed critical habitat designation. We removed 3.8 river miles and added 10 river miles to Unit 9 (Upper/Middle Tar River Subbasin) for a net change of 6.2 additional river miles. We removed 8.2 river miles from Unit 10 (Sandy/Swift Creek), added 3.5 river miles to Sturgeon Creek and 10.3 river miles to Nottoway River in Unit 4 (Nottoway River Subbasin). Further, we added 7 river miles to Unit 6 (Dan River). We created two new units based on the data received and the accidental omission, including the Sappony Creek Unit (Unit 3; 4 river miles) and the Little Grassy Creek Unit (Unit 8; 3 river miles). Addition of these units did not change the economic analysis, as both units are in counties that were included as part of the original analysis. We removed the originally proposed Unit 3 (Middle James River) because the VADWR data indicated that the Atlantic pigtoe does not currently occupy habitat in that part of the system; therefore, this unit no longer meets the criteria for designation as critical habitat as we determined that designation of unoccupied critical habitat is not essential for the conservation of the species (see Criteria Used to Identify Critical Habitat, below). All of these modifications were included in our reopening of the rule (85 FR 59487).

(9) Comment: The VADWR provided data for a newly recorded occurrence for Atlantic pigtoe, located approximately 500 meters (m) downstream of proposed critical habitat Unit 5. The commenter asked that the new information be recorded, but did not believe extending the proposed critical habitat another 500 to 600 m, in addition to the 8 km currently proposed for designation, would significantly benefit the conservation and recovery of Atlantic pigtoe. They also stated that potential delays in the proposed listing due to another reopening of the comment period on the critical habitat designation would be detrimental to the overall conservation and recovery of the species.

Our Response: The Service acknowledges receipt of the new occurrence record and appreciates the commenter's perspective on moving forward with listing and designation of critical habitat without delay. We concur that adding a small length of stream to an existing critical habitat unit would not be a significant benefit to the species, and would not contribute substantially to the previously identified strategy that we have deemed essential for the conservation of the species. We note that a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be valuable for recovery of the species. We have updated the SSA report accordingly.

(10) Comment: The SCDNR stated that our initial assumption that Atlantic pigtoe does not currently occur in South Carolina was incorrect. Specifically, the agency indicated that data do not exist to assert that South Carolina populations of Atlantic pigtoe are extirpated from the State. It mentioned the possibility that Atlantic pigtoe persists in areas of the State where it was thought to be historically, but has lacked concentrated survey efforts, especially in the Edisto and Pee Dee basins. The SCDNR indicated that survey efforts that have taken place are not adequate to determine the presence or absence of a rare species.

Our Response: We acknowledge the concerns of the SCDNR that targeted surveys for Atlantic pigtoe are needed in South Carolina watersheds. We updated the SSA report to include a statement that few surveys have been conducted in the Edisto and Pee Dee basins in South Carolina. However, based on current scientific information, the species has not been observed since the 1800s in South Carolina; therefore, we did not include areas in South Carolina as part of the currently occupied range. The Service will work closely with SCDNR and other States' agencies to evaluate priorities for data collection and monitoring related to the recovery of Atlantic pigtoe, including ensuring information is collected in South Carolina to make better determinations of presence/absence in South Carolina watersheds that would be informative for status reviews and recovery metrics.

(11) Comment: The SCDNR agreed with language of the proposed 4(d) rule's silvicultural exception ''to clarify that the BMPs [best management practices] must result in protection of the habitat features that provide for breeding, feeding, sheltering, and dispersal needs of the Atlantic pigtoe.'' However, the SCDNR recommended that we use the streamside management zones applied to Municipal Water Supplies in the Virginia BMP Technical Manual (2011), because they are more appropriate for protecting the species than those recommended for trout. They commented that BMPs that include these wider streamside management zones will minimize the impact of the silviculture activities including impacts from access roads and skid trails on the species by reducing sedimentation and protecting water quality by filtering excess nutrients.

Our Response: The Virginia BMP Streamside Management Zone (SMZ) widths for municipal water supplies, to which the SCDNR refers, are 100, 150, or 200 feet on each side of a waterbody (stream or lake), depending on the percent slope of adjacent lands (VDOF 2011, p. 15). While we acknowledge that the Virginia forestry BMP manual includes guidance for SMZ widths adjacent to municipal water supplies, we conclude that applying those, or the trout SMZs, in the 4(d) rule would introduce confusion among forest landowners and practitioners.

A primary reason for citing SMZs for trout in the preamble of our revised proposal (85 FR 59487; September 22, 2020) was that trout and the Atlantic pigtoe are similarly sensitive to sedimentation and thermal inputs. We acknowledge and agree with the SCDNR's point, supported by the scientific literature, that the sedentary nature of mussels renders them especially vulnerable to habitat degradation, including sedimentation and pollution (*e.g.,* ammonia, as mentioned in the comment letter). However, some resources (including Mayer et al. (2005), cited in SCDNR's letter) indicate that SMZ width alone may not be an effective measure of SMZ function. For example, buffer width significantly explained only 14 percent of a buffer's nitrogen removal effectiveness: ''forested and wetland buffers showed no relationship between buffer width and nitrogen removal effectiveness'' (Mayer et al. 2005, p. 5). While the Mayer study concluded that wider buffers were more consistently effective in nitrogen removal, it also concluded that other factors related to subsurface flow (*e.g.,* soil type, hydrology, biogeochemistry) were crucial. These findings regarding forested SMZ widths agree with those from the NCFS's most recent assessment of forestry BMPs; while the assessment found that wider buffers were generally associated with fewer risks to water quality, a model of the data showed a less than 10 percent probability of risk to water quality at buffer widths of 50 feet regardless of ecoregion (*i.e.,* Mountains, Piedmont, Coastal Plain), and that much narrower SMZ widths in some ecoregions achieved the same low probability of risk (Coats et al. 2017, p. 32), suggesting that there are more effective approaches to water quality protection in silviculture than prescribing a uniform SMZ width for all situations.

Our intent in the 4(d) rule for excepting incidental take resulting from forestry and silviculture activities is to relieve some regulatory burden on operations for which proper implementation of BMPs may offer a net conservation benefit. Therefore, based on the best available science and the comments we received, we have revised the 4(d) rule language to specify outcome-based management goals necessary for conservation of the species and its habitat to provide for the breeding, feeding, survival, and shelter of the Atlantic pigtoe, rather than prescribing a particular management practice with which to achieve necessary species and habitat protection (see II. Final Rule Issued Under Section 4(d) of the Act, below, for more information).

(12) Comment: During the first comment period, the NCFS suggested that it would be beneficial to focus only on BMPs and not include forest practice guidelines (FPGs) or forest certification standards in the 4(d) rule, because the FPGs and certification standards refer to State-approved BMPs as the guideline for management. Subsequently, during the second comment period, two commenters from State forestry agencies (VDOF and NCFS) offered alternative language for the entirety of the silvicultural component of the proposed 4(d) rule. They noted that this alternative language was drafted with the intent of applicability in targeted watersheds of the eastern Piedmont region and upper Coastal Plain region, where most of the Atlantic pigtoe's known current occupancy and proposed critical habitat is located. They also noted that their alterative language may be useful in other future listings of aquatic species. The suggested alternative language for the 4(d) rule exception follows: ''Forestry-related activities, including silvicultural practices, forest management work and fire control tactics, that achieve all of the following: 1. Establish a streamside management zone alongside the margins of each occupied waterway. 2. Restrain visible sedimentation caused by the forestry-related activity from entering the occupied waterway. 3. Maintain groundcover within the streamside management zone of the occupied waterway, and promptly re-establish groundcover if disturbed. 4. Limit installation of new vehicle or equipment crossings of the occupied waterway to only where necessary for the forestry-related activity. Such crossings shall: (a) Have erosion and sedimentation control measures installed to divert surface runoff away and restrain visible sediment from entering the waterway; (b) Allow for movement of aquatic organisms within the waterway; and (c) Have groundcover applied and maintained through completion of the forestry-related activity. 5. Prohibit the use of tracked or wheeled vehicles for reforestation site preparation within the streamside management zone of the occupied waterway. 6. Prohibit locating log decks, skid trails, new roads, and portable mill sites in the streamside management zone of the occupied waterway. 7. Prohibit obstruction and impediment of the flow of water within the occupied waterway, caused by direct deposition of debris or soil by the forestry-related activity. 8. Maintain shade over the occupied waterway similar to that observed prior to the forestry-related activity. 9. Prohibit discharge of any solid waste, petroleum, pesticide, fertilizer, or other chemical into the occupied waterway.''

Our Response: The Service appreciates the constructive communications with State forestry agencies during the public comment periods, their willingness to express the challenges that the proposed 4(d) rule posed for implementation and forestry operation oversight, and their collaborative effort to offer alternative 4(d) rule language that will be more straightforward to implement and communicate to forestry practitioners. Importantly, the language offered by the NCFS and VDOF during the second comment period also conveys the necessity of achieving the water quality outcomes the Service intended for the protection of Atlantic pigtoe and its habitat, while reducing the regulatory burden associated with strict adherence to the 4(d) rule's provisions. We have revised the 4(d) rule language to reflect these suggested changes for the forestry exception (see Summary of Changes from the Proposed Rule, below).

Public Comments

(13) Comment: Several comments we received, both from the public and from three State forestry agencies (VDOF, NCFS, and SC Forestry Commission (SCFC)), indicated the Service did not explain or justify the necessity for two-zoned SMZs, for SMZs wider than those already recommended by State forestry BMPs within the geographic range of the Atlantic pigtoe, or for SMZs related to Virginia and North Carolina trout waters being applied to the majority of waters where the Atlantic pigtoe occurs. Some comments further suggested that references to trout rules or BMPs beyond those already required within the range of the Atlantic pigtoe would be confusing and challenging to implement. Several such comments further questioned any additional conservation benefit that SMZs wider than those currently recommended in State BMPs would provide.

Our Response: In the preamble of our September 22, 2020, proposed rule (85 FR 59487), we addressed comments we received on the October 11, 2018, proposed rule (83 FR 51570), that stated the proposed 4(d) language related to ''highest standard BMPs'' was too vague or confusing. In the September 22, 2020, proposed rule, it was our intent to provide additional discussion and detail for the proposed 4(d) incidental take exception resulting from silviculture. By referring to BMPs related to trout waters, specifically SMZs, we intended to use a frame of reference that would be familiar to forest landowners for species sensitive to sedimentation and thermal effects on stream waters. The proposed regulation text in the September 22, 2020, proposed rule outlined BMPs, but did not include references to trout. However, we understand that the references to trout waters in the preamble of that document has caused considerable confusion for multiple reasons, including: (1) The Atlantic pigtoe mostly occurs in watersheds absent of trout; (2) the preamble did not clearly state how the Atlantic pigtoe is similarly sensitive to sedimentation (a primary factor responsible for the adoption of BMPs specific to trout waters); and (3) multiple other regulations and recommended practices already exist in watersheds where the Atlantic pigtoe occurs (*e.g.,* region-specific State BMPs, riparian buffer rules in some watersheds). We have carefully considered and addressed the concerns of the commenters by revising the final 4(d) rule to specify the outcome-based habitat management goals necessary to provide habitat for the breeding, feeding, survival, and sheltering of the Atlantic pigtoe, rather than prescribing a particular management practice with which to achieve necessary habitat protection (*e.g.,* we removed the two-zoned SMZs of variable width; see II. Final Rule Issued Under Section 4(d) of the Act and Regulation Promulgation, below, for more information).

(14) Comment: We received many comments, from both the public and from State forestry agencies (SCFC and VDOF), noting that State-approved BMPs are sufficient for the protection of the Atlantic pigtoe. These commenters also maintained that mandatory adoption of BMPs is not necessary as BMP implementation rates are already high.

Our Response: When properly implemented, BMPs can offer a substantial improvement to water quality compared to forestry operations where BMPs are not implemented or not properly implemented; therefore, we have included an exception for incidental take resulting from silviculture and forest management in the final 4(d) rule. Intact riparian buffers (*i.e.,* SMZs) have been cited as important contributing factors for protecting mussels against excess sedimentation and nutrient input from a variety of consumptive land uses (O'Driscoll et al. 2014, pp. 87–90; Osterling and Hogberg 2014, p. 219). Streams with forested buffers have been shown to have greater mussel species evenness; less ammonia, nitrogen, and solar radiation input; and less fluctuation of daily temperatures than streams with narrow, grassy riparian zones (Morris and Corkum 1996, pp. 580–584).

The commenters also provided information that indicates forestry BMP implementation across the nation and Southeast region are generally high; we agree, but assert that implementation of effective BMPs in forest management is not universal. A 2018 report by the Southern Group of State Foresters (SGSF) shows that overall BMP implementation rates have increased over the last 20 years, more markedly in some States than in others (*e.g.,* BMP implementation in Virginia was the lowest of all the southeastern States (76 percent) as recently as 2007, but increased to 94 percent by 2016 (SGSF 2018, p. 10)). Virginia's most recent BMP monitoring report indicated that audits of 240 sites in 2018 resulted in findings of significant water quality risk in only four cases, and that none of them had active sedimentation during the audit visit (VDOF 2020, p. 3). However, they also reported that despite overall high BMP implementation rates, three very important categories that often lead to water quality concerns (roads, crossings, and skid trails), sometimes lag behind other categories with regard to implementation percentage (VDOF 2020, p. 3). Data from the SGSF show North Carolina has the lowest overall implementation rate (84 percent) in the Southeast, with other State implementation rates ranging from 89 to 99 percent (SGSF 2018, p. 10). The most recent survey of BMP implementation in North Carolina showed that implementation rates—while averaging 84 percent Statewide—varied among regions within the State, and with respect to the type of BMP being evaluated (Coats 2017, pp. 8–41). The NCFS reported that BMPs were not applied or properly implemented in 4,584 opportunities in their assessments, and that 30 percent of these cases posed a risk to water quality (Coats 2017, p. 8). The NCFS also reported that 74 percent of all identified risks to water quality were associated with the lack of application or improper implementation of BMPs related to stream crossings (average implementation rate = 79 percent; range 72–83 percent), SMZs (average implementation rate = 86 percent; range 72–91 percent), and post-harvest rehabilitation of a site (average implementation rate = 71 percent; range 53–83 percent) (Coats 2017, pp. 8, 9, 18–19, 26–34). Such incidents of improperly or unused BMPs and their associated risks to water quality and habitat, as illustrated by these reports, are important to acknowledge in the context of rare, imperiled species, where any one particular localized event may result in further imperilment of a population or hamper recovery of the species.

Development and refinement of BMPs has resulted in substantial improvements to forestry's impacts on water quality in recent decades and has created a culture of water stewardship in the forest landowner community, making this stakeholder group an important ally in the conservation of imperiled species. The reduced risks to water quality justify our inclusion of a 4(d) incidental take exception resulting from forestry and silviculture for the Atlantic pigtoe, but the remaining presence of sedimentation risk supports the need to specify conditions required for the exception to apply. Forest management activities in the range of the Atlantic pigtoe that are not expected to meet the conditions of the 4(d) rule exception could still occur via consultation with the Service under section 7 or a conservation agreement under section 10 of the Act.

Existing BMPs will be sufficient for the protection of the Atlantic pigtoe if they are widely implemented in watersheds where the species occurs and are implemented appropriately such that forest management operations maintain compliance with State regulatory requirements, and that they achieve management goals related to conserving and maintaining suitable habitat for the Atlantic pigtoe, which closely mirror State forestry regulations on water quality. State-approved BMPs, properly implemented, protect water quality and help conserve aquatic species, including the Atlantic pigtoe. Forest landowners who properly implement those BMPs are helping conserve the species, and this final 4(d) rule is an incentive for all landowners to properly implement those BMPs to avoid any possible take liability. Further, those forest landowners who are third-party-certified to a credible forest management standard are providing audited certainty that BMPs are being implemented across the landscape.

(15) Comment: Some of the comments concerning BMPs also suggested that assessments of water quality using aquatic insects as indicators confirm that BMPs are protective of water quality and habitat for aquatic species.

Our Response: Much of the literature shared by commenters on the effectiveness of BMPs for protecting aquatic species and their habitats relies on aquatic macroinvertebrate assessments, mostly of aquatic insects. While they are a common rapid field assessment method for monitoring or measuring water quality, current scientific information does not support the assertion made by several commenters that presence or recovery of insects is a proxy for suitable habitat recovery after disturbance (*i.e.,* a sedimentation event) for benthic invertebrates like the Atlantic pigtoe, or a proxy for recolonization of mussels after such a disturbance. While reliance on effects to aquatic insect communities is a useful rapid assessment tool for water quality, there is a gap in the best available science about how that resilience relates to comparatively long-lived animals, such as unionid freshwater mussels (*e.g.,* the Atlantic pigtoe). Some research comparing how macroinvertebrate insect assessments relate to other taxa (*e.g.,* amphibians, fishes, zooplankton) indicates that insect assessments do not correspond well in evaluations of watershed land use or anthropogenic effects on water quality and water resources for these species (*e.g.,* Brazner et al. 2007, pp. 625–627; Kovalenko et al. 2019, entire; Herlihy et al. 2020, entire). Further, some studies recommend using assessments from multiple taxa to better evaluate the response of biological integrity in streams to anthropogenic activities (Herlihy et al. 2020, p. 10; Hughes et al. 2000, pp. 437–440). The risks of water quality impacts to many taxa are emphasized in studies, highlighting the utility of aquatic insect assessments for evaluating forestry BMPs, along with the need for research on forestry BMP effectiveness for the protection of taxa other than aquatic insects (Warrington et al. 2017, entire). Freshwater mussels have been recognized for decades as important for biomonitoring of environmental health

because of their sedentary nature, long lifespans, and complex life history (Van Hassel and Farris 2007, entire).

A number of other differences between aquatic insects and unionid mussels makes comparisons of their responses to water quality tenuous and demands careful consideration in applying the results from one to the other. Most aquatic insects (particularly those widely used in assessments) are not rare species; thus, the impact of any single or isolated event is likely to be more easily masked at the population level. Further, the aquatic larval phase of macroinvertebrate insects typically emphasized in assessments is of short duration (*e.g.,* aquatic phases ranging less than 1 to 2 years for many mayflies (Ephemeroptera; Voshell 2002, p. 270); 1 to 2 years for many stoneflies (Plecoptera; Voshell 2002, p. 310); less than 1 to 2 years for most caddisflies (Trichoptera; Voxhell 2002, p. 375)) and acute effects in the recent past (less than 5 years) may not present in assessment data. This is facilitated by the immigration of aquatic insects back into impacted stream reaches by downstream drift or other mechanisms, including the adult winged flight stage, which allows immigration from other nearby waterbodies or from downstream reaches (Waters 1972, entire).

Conversely, Atlantic pigtoe is a rare, sedentary mussel living in stream bed substrates, with different ecological requirements and a decades-long lifespan. Extirpation of Atlantic pigtoe from a stream reach after an impact to the population (*e.g.,* a sedimentation event that suffocates mussels in the stream bed or impairs reproduction in a given year) would have longer lasting consequences, and recolonization can be hampered by many factors, such as: The Atlantic pigtoe's typically small population sizes, low reproductive success, instream barriers to the migration of host fishes, distance between populations that can serve as potential recolonization sources, and long generation time (approximately 10 to 12 years; Service 2021, p. 66). Again, we recognize that widespread implementation of BMPs has unquestionable benefits to water quality and likely Atlantic pigtoe habitat; however, we also recognize that additional quantification of the effects of BMPs on mussels would be valuable, particularly given the differential life history characteristics between macroinvertebrate taxa.

(16) Comment: Some commenters stated that the Service did not provide evidence that the Atlantic pigtoe is a sensitive species, and at least one commenter stated that failure to describe its sensitivity or similarity to trout sensitivity is arbitrary and capricious.

Our Response: In our October 11, 2018, proposed rule (83 FR 51570), we included several details related to the ecological requirements of the Atlantic pigtoe (*e.g.,* high dissolved oxygen, silt-free substrates), referenced the SSA report, and included a summary of risk factors to the species (*e.g.,* primarily habitat degradation, including the buildup of fine sediments, the loss of flowing water, instream habitat fragmentation, and impairment of water quality). In our September 22, 2020, revisions to the proposed rule (85 FR 59487), we provided additional information, including statements on the effects of sedimentation to the Atlantic pigtoe (*e.g.,* Silted stream bottoms suffocate filter feeding animals and decrease the stream's insect population, an important source of food for host fish (VDOF 2011, p. 37). Siltation also makes mussel and host fish reproduction difficult (Service 2021, pp. 29, 41, 47, 57). Transformed juvenile mussels require clean gravel/coarse sand substrates with oxygenated water to successfully become adults (Service 2021, p. 11). Lastly, a silted bottom substrate can result in mortality (Service 2021, pp. 29, 59)). (see 85 FR 59490). The September 22, 2020 revisions to the proposed rule were specific to the 4(d) rule and designation of critical habitat, and it directed readers to the initial listing proposal, the SSA report, and previous Federal actions for additional detailed information about the Atlantic pigtoe. The commenters may not have realized that the September 22, 2020, document discussed a subset, but did not repeat the entirety, of the proposals published in the October 11, 2018, proposed rule; the focus of the September 22, 2020, document was on the substantive revisions proposed. However, the concerns of the commenters have been carefully considered and are addressed in this rule by removing references to trout and providing more detailed information about the Atlantic pigtoe, its habitat requirements, and its sensitivity to threats, particularly sedimentation, using the best available scientific information about this species and relevant information from related species (*i.e.,* freshwater bivalves).

(17) Comment: A few commenters highlighted proposed or final rules for other aquatic species that they say indicate a Service precedent for accepting State-approved forestry BMPs as sufficient for protection of a species in a 4(d) rule's exceptions, and that they think that approach should also apply to the Atlantic pigtoe's 4(d) rule.

Our Response: All 4(d) rules establish species-specific regulations to provide for the conservation of a threatened species and must be considered within the context of that species' needs. Because all species are unique, measures included in some 4(d) rules should not be considered to set a precedent for future 4(d) rules on other species. Although it may be practical to consider the implications of how 4(d) rules are implemented for species with overlapping geographic ranges and habitat needs, we still must ensure that each 4(d) rule establishes the regulations necessary and advisable to provide for the conservation of species listed as threatened. We also note that several of the commenters' examples do not apply to threatened species or are not from a 4(d) rule. For example, commenters referenced language in the preamble of the final rule listing the Black Warrior waterdog (*Necturus alabamensis*) as an endangered species and designating critical habitat (83 FR 257; January 3, 2018) that refers to Alabama's forestry BMPs in the Summary of Factors Affecting the Species discussion. Other comments we received referred to BMP discussions not for species' listing actions but for critical habitat designations (*e.g.,* candy darter (*Etheostoma osburni*), diamond darter (*Crystallaria cincotta*), and big sandy crayfish (*Cambarus callainus*)) that listed BMPs among activities that can ameliorate threats to critical habitat. Comments also referenced the pearl darter (*Percina aurora*), a species listed as threatened in 2017 (82 FR 43885; September 20, 2017) when our regulations at 50 CFR 17.31 applied to threatened species all of the provisions of 50 CFR 17.21 for endangered species unless we promulgated species-specific provisions under section 4(d) of the Act for the threatened species; the pearl darter listing rule (82 FR 43885; September 20, 2017) included silviculture with BMPs among actions unlikely to result in a violation of the Act's section 9, and that rule also discussed poor silviculture under the Summary of Factors Affecting the Species. Finally, some comments referenced the trispot darter (*Etheostoma trisella*), which is a threatened species listing with a species-specific 4(d) rule that includes an exception for silviculture. The final 4(d) rule for the trispot darter (85 FR 61619; September 30, 2020) has an incidental take exception for silviculture practices and forest management activities that includes

requirements for implementing State BMPs for SMZs, stream crossings, and forest roads, among others; removing logging debris from stream channels; and limiting activities to only a portion of the year if they involve spawning habitat. Although the trispot darter 4(d) rule is the most similar among the commenters' examples to this rule for the Atlantic pigtoe (*i.e.,* a threatened species listing rule with a 4(d) rule incidental take exception for silviculture), we are required to tailor the 4(d) rule to the Atlantic pigtoe, based on what is necessary and advisable to provide for the conservation specifically of the Atlantic pigtoe. Furthermore, a mobile darter has a different life history than a sessile freshwater mussel, and likewise has different responses to sedimentation or water quality inputs. The Service considers existing local environmental rules, local environmental conditions, and other factors, *in toto,* and tailors regulations to the management needs of species within that context to ensure prohibitions and exceptions to prohibitions for threatened species outlined in 4(d) rules are specific to the considerations for each particular species.

(18) Comment: Two comments expressed concern that, if the proposal were made final with forest management requirements in the 4(d) rule's exceptions that exceed State-recommended BMPs for the areas in which the Atlantic pigtoe occurs, the 4(d) rule for the Atlantic pigtoe would set a precedent not founded in the best available scientific information.

Our Response: See our response to *(17) Comment,* above. The species-specific nature of 4(d) rules is inherently incompatible with setting precedents because we must consider the needs of the individual species being listed within each rule. The Atlantic pigtoe's 4(d) rule does not prescribe management restrictions; rather, it provides for the conservation of the species by outlining prohibitions (*e.g.,* take) that are compatible with the overall conservation of the species, and sets forth exceptions to those prohibitions for activities that are expected not to impede conservation. The Atlantic pigtoe's 4(d) rule's exceptions to prohibitions provide specific information on the conditions required for being excepted from incidental take resulting from certain activities. The 4(d) rule does not prohibit silvicultural management; activities resulting in incidental take not included in the 4(d) rule's exceptions to prohibitions could still be covered under a conservation agreement under section 10 of the Act or authorized via section 7 of the Act. The 4(d) rule's incidental take exceptions are intended to provide some relief from regulatory burden, while outlining the conditions necessary and advisable for the conservation of the species.

As discussed above (see our response to *(13) Comment,* above), we have revised the 4(d) rule by removing the two-zoned SMZ requirement over concerns related to confusion and challenging implementation of multiple sets of forestry-related rules and guidelines already in place within the geographic range of the Atlantic pigtoe.

(19) Comment: During the first public comment period, two commenters noted that the meaning of ''highest-standard'' BMPs as stated in the proposed 4(d) rule is unclear. They indicate that each forestry BMP stands on its own merits; there are not different classes or degrees or standards of BMPs. Indeed, on some sites, it may be adequate to apply a limited number of BMPs, while on other sites, a more comprehensive set of BMPs may be appropriate. One of the commenters suggested that to avoid confusion, the 4(d) rule should say, ''State-approved best management practices'' or an equivalent phrase.

After revisions to the 4(d) rule, during the second comment period, several commenters requested that we revise the proposed 4(d) rule to ''only reference State-approved BMPs without addition or modification.'' Another commenter (NCFS) suggested an alternative to incorporate by reference a section of the Code of Federal Regulations (CFR) related to compliance with the exemption from permitting to discharge dredged or fill material into waters of the United States (*i.e.,* 33 CFR 323.4(a)(6)(ix): The discharge shall not take, or jeopardize the continued existence of, a threatened or endangered species as defined under the Endangered Species Act, or adversely modify or destroy the critical habitat of such species.) The NCFS asserted that a 4(d) rule for the Atlantic pigtoe should be written to cross-reference these existing Federal regulations and apply concurrent compliance with the requirements of both the Clean Water Act (CWA; 33 U.S.C. 1251 *et seq.*) and Endangered Species Act, through a blanket section 7 consultation.

Our Response: In response to the comments from the first public comment period, we modified the proposed 4(d) rule language to provide specific details for SMZ widths that will be most protective of the habitat for the species (85 FR 59487; September 22, 2020), similar to those ''more substantial'' BMPs considered for streams that are designated ''trout waters'' and already implemented by both Virginia's and North Carolina's State forestry programs. We also modified the 4(d) rule language to use the phrase ''State-approved BMPs'' as suggested by the original commenter.

In response to additional comments we received during the second comment period (specifically those suggesting reference to the U.S. Army Corps of Engineers' regulations at 33 CFR 323.4(a)(6)(ix), which set forth exemptions for CWA permitting requirements for the construction of farm roads, forest roads, or temporary roads for moving mining equipment), we find that these regulations are not designed to conservation species such as Atlantic pigtoe. The CFR reference suggested by the commenter is provides no specific guidance on implementing the exempted activities to avoid take of or jeopardy to endangered or threatened species. The use of State-approved BMPs for forestry to meet the CWA exemption are not species conservation regulatory requirements. Furthermore, State forestry BMP manuals do not represent a law or requirement; they are a set of recommended practices for achieving compliance with water quality regulations, and BMP manuals are subject to change. In fact, the NCFS has recently proposed revisions to the NC BMP manual (Gerow 2020, pers. comm.); this highlights the need to provide specific information for the conservation of a species in the text of the 4(d) rule. It is the responsibility of the Service under the Endangered Species Act to provide guidance on how to avoid take of or jeopardy to endangered and threatened species, and the Act guides the Service to establish a species-specific 4(d) rules for threatened species, including language stating prohibitions and exceptions to prohibitions for the protection of the species.

Finally, nothing in this final 4(d) rule will change in any way the consultation requirements under section 7 of the Act. However, interagency cooperation may be further streamlined through planned programmatic consultations for the species between Federal agencies and the Service, where appropriate.

(20) Comment: Two commenters stated that SMZs are part of a suite of BMPs and that they should not be proposed alone.

Our Response: We proposed the incidental take exception resulting from forestry to include multiple State-approved BMPs, highlighting considerations for SMZs because of their importance to stream habitat, along with considerations for stream

crossings, skid trails, and access roads. However, commenters have demonstrated particular concern and confusion over that portion of the proposed incidental take exception resulting from forestry activities with specifications on SMZs. As noted in our response to *(13) Comment,* above, we have revised the 4(d) rule's incidental take exception to include the suite of BMPs.

(21) Comment: During the first comment period, the NCFS commented that forestry-related, site-disturbing activities must protect riparian areas, indicating that the multiple layers of existing State-enacted riparian zone protections are sufficient to restrain sediment from negatively impacting habitat for the Atlantic pigtoe and other species. They referenced a U.S. Department of Agriculture study demonstrating that the use of BMPs and compliance with the State's standards effectively maintained water quality and sustained the populations of benthic macroinvertebrates, and noted that the results from this study demonstrate that forestry operations will not impact Atlantic pigtoe habitat. They recommended that compliance with State-enacted riparian buffer rules should be deemed as concurrent compliance with the 4(d) rule's prohibitions as well as concurrent protection of critical habitat. In addition, we received several comments indicating that a 4(d) rule that includes overly specific prescriptive measures for protecting water quality and habitat for the Atlantic pigtoe would be confusing to communicate to landowners and challenging to implement.

Our Response: State regulations are susceptible to change (as described in the SSA report, section 4.2); therefore, it is necessary to detail the requirements needed for the Atlantic pigtoe in the Federal listing rule, which includes the 4(d) rule. The reference to the paired watershed study is not specifically relevant to the Atlantic pigtoe, as that study focused on water quality only (not instream or streamside habitat) and impacts to benthic macroinvertebrates that did not include freshwater mussels. Therefore, in our 4(d) rule, we articulate outcome-based habitat management that, if followed, will eliminate sedimentation threats to Atlantic pigtoe habitat and is excepted from incidental take prohibitions.

(22) Comment: One commenter recommended that the Service remove from the descriptions of critical habitat units references to silviculture being a potential source of pollution. The commenter indicated that the forestry sector in general believes that such references may have had some credence a generation or more ago, but the advent of BMPs, their proven effectiveness, and high implementation rates make such references incorrect today.

Our Response: The best available science indicates that proper implementation of forestry BMPs reduces negative effects on water quality compared to historical silvicultural practices and compared to current practices that do not apply or properly implement BMPs. However, although BMPs generally are implemented at high rates, they are not universally applied or always properly implemented, and forest management activities can still contribute to high sediment loads. As noted above, the most recent assessment of BMP implementation by the NCFS reported that the majority of risks to water quality identified during the assessment were associated with forest managers' failure to use or properly apply BMPs related to SMZs, stream crossings, and post-harvest restoration (Coats 2017, pp. 8–34). We also acknowledge that there are multiple sources of sediment and other pollutants. That said, we have removed from the critical habitat descriptions the statements about silvicultural runoff as a source of pollution, and we have replaced them with language about management activities that will benefit habitat for the species, such as riparian buffer restoration, reduced surface and groundwater withdrawals, stormwater retrofits, elimination of direct stormwater discharges, and implementation of the highest levels of wastewater treatment practicable.

(23) Comment: One commenter noted that the Service's proposed critical habitat designation for the Atlantic pigtoe is inadequate to ensure the conservation of the species because the Service has only proposed critical habitat within the species' currently occupied habitat, neglecting the essential protection of unoccupied habitat pursuant to 16 U.S.C. 1532(5)(A)(ii).

Our Response: We did not propose to designate any areas outside the geographical area currently occupied by the species because we did not find any unoccupied areas to be essential for the conservation of the species. We have determined that the designation of critical habitat within eight occupied management units currently categorized as moderately or highly resilient across the physiographic representation of the species' range will conserve the species. Efforts to improve the resiliency of populations in currently occupied streams should increase viability to the point that the protections of the Act are no longer necessary. See Criteria Used to Identify Critical Habitat, below, for more information.

(24) Comment: One commenter noted that the Service's failure to protect as critical habitat the currently unoccupied habitat across Georgia, South Carolina, North Carolina, and Virginia that soon may be subject to anticipated State restocking efforts undermines the Service's charge under the Act to fashion a concerted regulatory scheme to ensure the long-term viability of this species by bolstering its range and resiliency. The commenter called upon the Service to designate suitable, unoccupied critical habitat in each of the 12 river basins in the Atlantic pigtoe's historical range to prevent the further deterioration of their once-and-future habitat.

Our Response: We are working in coordination with State efforts to re-establish extirpated Atlantic pigtoe populations via captive propagation. Designation of critical habitat is not required for these species restoration efforts, and as discussed above (see our responses to *(8) Comment* and *(23) Comment,* above), we have determined that designation of unoccupied critical habitat is not essential for the conservation of the species. In our final 4(d) rule for the Atlantic pigtoe, we are excepting incidental take resulting from captive propagation and reintroduction efforts, as we recognize these efforts further the conservation of the species. Excepting incidental take resulting these activities under the 4(d) rule enables each State to proceed with stocking that is not subject to incidental take. In addition, section 6 of the Act provides that the Service shall cooperate to the maximum extent practicable with the States in carrying out programs authorized by the Act. Therefore, the final 4(d) rule also provides that any qualified employee or agent of a State conservation agency that is a party to a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by his or her agency for such purposes, would be able to conduct activities designed to conserve Atlantic pigtoe that may result in otherwise prohibited take without additional authorization.

I. Final Listing Determination

Background

Please refer to the October 11, 2018, proposed rule (83 FR 51570), the September 22, 2020, document (85 FR 59487), and the SSA report for a full summary of species information. These documents are available at *http://*

www.regulations.gov under Docket No. FWS–R4–ES–2018–0046.

The Atlantic pigtoe is a small freshwater mussel with a sub-rhomboidal shaped shell. Although larger specimens exist, the Atlantic pigtoe rarely exceeds 50 millimeters (mm) (2 inches (in)) in length. The known historical range of the Atlantic pigtoe included 12 populations in Atlantic river basins from Virginia to Georgia. However, surveys conducted from 2005 to 2019 indicate that the currently occupied range of the Atlantic pigtoe consists of seven populations in Virginia and North Carolina. The Atlantic pigtoe is dependent on clean, moderate-flowing water with high dissolved oxygen content in creek and riverine environments. Historically, the most abundant populations existed in creeks and rivers with excellent water quality, and where stream flows were sufficient to maintain clean, silt-free substrates. It is associated with gravel and coarse sand substrates at the downstream edge of riffles (shallow water with rapid currents running over gravel or rocks), and less commonly occurs in cobble, silt, or sand detritus mixtures. Because this species prefers more pristine conditions, it typically occurs in headwaters of rural watersheds.

The Atlantic pigtoe is presumed to be an omnivore. Adults primarily filter feed on a wide variety of microscopic particulate matter suspended in the water column, including phytoplankton, zooplankton, bacteria, detritus, and dissolved organic matter, although juveniles tend to pedal feed in the sediment (Alderman and Alderman 2014, p. 9). Like most freshwater mussels, the Atlantic pigtoe has a unique life cycle that relies on fish hosts for successful reproduction. Following release from the female mussel, sticky packets of floating glochidia (larvae) attach to the gills and scales of host minnows. The larvae stay attached to the host fish until they complete metamorphosis, when they release from the fish and fall to the substrate.

The Atlantic pigtoe has been documented in all major river basins in the Atlantic coastal drainages from the James River Basin in Virginia south to the Altamaha River Basin in Georgia, and from the foothills of the Appalachian Mountains to the Coastal Plain. However, abundance and distribution of the species has declined, with the species currently occupying approximately 40 percent of its historical range. Most of the remaining populations are small and fragmented, only occupying a fraction of reaches that were historically occupied. Recent surveys found Atlantic pigtoes remain in seven populations in Virginia and North Carolina; however, only three populations have multiple documented occurrences within the past 16 years. This decrease in abundance and distribution has resulted in largely isolated contemporary populations. Evidence suggests that the range reduction of the species corresponds to habitat degradation resulting from the cumulative impacts of land use change and associated watershed-level effects on water quality, water quantity, habitat connectivity, and instream habitat suitability.

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an ''endangered species'' or a ''threatened species.'' The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an ''endangered species'' or a ''threatened species'' because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as the Service can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity,

certain behaviors, and other demographic factors.

Our proposed rule described ''foreseeable future'' as the extent to which we can reasonably rely on predictions about the future in making determinations about the future conservation status of the species. The Service since codified its understanding of foreseeable future at 50 CFR 424.11(d) (84 FR 45020; August 27, 2019). In those regulations, we explain the term ''foreseeable future'' extends only so far into the future as the Service can reasonably determine that both the future threats and the species' responses to those threats are likely. The Service will describe the foreseeable future on a case-by-case basis, using the best available data and taking into account considerations such as the species' life-history characteristics, threat-projection timeframes, and environmental variability. The Service need not identify the foreseeable future in terms of a specific period of time.

These regulations did not significantly modify the Service's interpretation of the term ''foreseeable future''; rather they codified a framework that sets forth how the Service will determine what constitutes the foreseeable future based on our long-standing practice. However, the regulations at 50 CFR 424.11(d) do not apply to this final rule because the October 11, 2018, proposed rule for the Atlantic pigtoe (83 FR 51570) published prior to the effective date of the final rule amending 50 CFR 424.11(d) (84 FR 45020; August 27, 2019). Our assessment of the ''foreseeable future'' for the Atlantic pigtoe, as presented in our October 11, 2018, proposed rule and this final rule, has not changed.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species. The SSA report does not represent a decision by the Service on whether the species should be listed as an endangered or threatened species under the Act. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies. The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at *http://www.regulations.gov* under Docket No. FWS–R4–ES–2018–0046.

To assess Atlantic pigtoe viability, we used the three conservation biology principles of resiliency, redundancy, and representation (the ''3 Rs'') (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency supports the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years), redundancy supports the ability of the species to withstand catastrophic events (for example, droughts, large pollution events), and representation supports the ability of the species to adapt over time to long-term changes in the environment (for example, climate changes). In general, the more resilient and redundant a species is and the more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

The SSA process can be divided into three sequential stages. During the first stage, we evaluated the individual species' life-history needs. In the next stage, we assessed the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. In the final stage, we made predictions about the species' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we used the best available information to characterize viability as the ability of a species to sustain populations in the wild over time. We use this information to inform our regulatory decision.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the species and its resources, and the threats that influence the species' current and future condition, in order to assess the species' overall viability and the risks to that viability.

To evaluate the current and future viability of the Atlantic pigtoe, we assessed a range of conditions to allow us to consider the species' resiliency, representation, and redundancy. Populations were delineated using the 12 river basins that Atlantic pigtoe mussels historically occupied: The James, Chowan, Roanoke, Tar, Neuse, Cape Fear, Pee Dee, Catawba, Edisto, Savannah, Ogeechee, and Altamaha River basins. Because the river basin level is at a very coarse scale, populations were further delineated using management units (MUs). The MUs were defined as one or more U.S. Geological Survey Hydrological Unit Code (HUC) 10 watersheds that species experts identified as the most appropriate unit for assessing population-level resiliency. To provide context for the current condition of the species using the 3 Rs, we considered the historical range as context for the species' resiliency, redundancy, and representation on the landscape in the past. However, in addressing the current condition of the 3 Rs, only extant populations were analyzed.

To assess resiliency, we qualitatively analyzed data related to three population factors (MU occupancy, recruitment, and abundance) and four habitat elements (water quality, water quantity/flow, instream substrate, and habitat connectivity). Overall population condition rankings and habitat condition rankings were determined by combining these factors and elements.

We described representation for the Atlantic pigtoe in terms of river basin variability (known from 12 historical river basins, currently extant in 7), physiographic variability (Mountains, Piedmont, and Coastal Plain), and historical latitudinal variability (Virginia south to Georgia). We assessed Atlantic pigtoe redundancy by first evaluating occupancy within each of the hydrologic units (*i.e.,* HUC10s) that constitute MUs, and then evaluating occupancy at the MU, and ultimately the population level.

Factors Influencing Atlantic Pigtoe Viability

Aquatic systems face a multitude of natural and anthropogenic factors that may impact the status of species within those systems (Neves et al. 1997, p. 44). Generally, these factors can be categorized as either environmental stressors (*e.g.,* development, agriculture practices, improper forest management) or systematic changes (*e.g.,* climate change, invasive species, dams or other barriers). The largest threats to the future viability of the Atlantic pigtoe consist of habitat degradation from stressors influencing water quality, water quantity, instream habitat, and habitat connectivity. All of these threats are exacerbated by the effects of climate change. A brief summary of these primary stressors is presented below; for a full description of these stressors, refer to chapter 4 of the SSA report (Service 2021, pp. 45–61). We did not find that the species faces significant threats from overutilization for commercial,

recreational, scientific, or education purposes, or from disease or predation.

Environmental Stressors

Development: Development refers to urbanization of the landscape, including (but not limited to) land conversion for urban and commercial use, infrastructure (roads, bridges, utilities), and urban water uses (water supply reservoirs, wastewater treatment, etc.). The effects of urbanization may include alterations to water quality, water quantity, and habitat (both in stream and streamside) (Ren et al. 2003, p. 649; Wilson 2015, p. 424). These alterations adversely affect both Atlantic pigtoe adults, which require clear, flowing water with a temperature less than 35 degrees Celsius (°C) (95 degrees Fahrenheit (°F)) and a dissolved oxygen greater than 3 milligrams per liter (mg/L), and juveniles, which require very specific interstitial chemistry to complete that life stage: Low salinity (similar to 0.9 parts per thousand (ppt)), low ammonia (similar to 0.7 mg/L), low levels of copper and other contaminants, and dissolved oxygen greater than 1.3 mg/L.

Impervious surfaces associated with development negatively affect water quality when pollutants that accumulate on impervious surfaces are washed directly into the streams during storm events. Storm water runoff affects such water quality parameters as temperature, pH, dissolved oxygen, and salinity, which in turn alter the water chemistry and could make habitat unsuitable for the Atlantic pigtoe. Concentrations of contaminants, including nitrogen, phosphorus, chloride, insecticides, polycyclic aromatic hydrocarbons, and personal care products, increase with urban development (Giddings et al. 2009, p. 2; Bringolf et al. 2010, p. 1311).

Urban development can also lead to increased variability in streamflow, typically increasing the amount of water entering a stream after a storm and decreasing the time it takes for the water to travel over the land before entering the stream (Giddings et al. 2009, p. 1). Stream habitat is altered either directly via channelization or clearing of riparian areas, or indirectly via high stream flows that reshape the channel and cause sediment erosion (Giddings et al. 2009, p. 2). Impervious surfaces associated with increased development cause rain water to accumulate and flow rapidly into storm drains, thereby becoming overheated, which can stress or kill mussels when it enters streams. Pollutants like gasoline, oil, and fertilizers are also washed directly into streams and can kill mussels and other aquatic organisms. The large volumes and velocity of water, combined with the extra debris and sediment entering streams following a storm, can stress, displace, or kill Atlantic pigtoes and the host fish species on which they depend. Many of the known host fish of the Atlantic pigtoe can tolerate short periods of turbidity associated with rain events; however, the cyprinid host fish typically do not persist in streams with consistently high sedimentation. Changes in flow may also result in turbidity that can reduce feeding efficiency and eliminate spawning habitat due to lack of clean gravel substrate.

A further risk of urbanization is the accompanying road development that often results in improperly constructed culverts at stream crossings. These culverts act as barriers, either if flow through the culvert varies significantly from the rest of the stream, or if the culvert ends up being perched above the stream bed so that host fish (and, therefore, the Atlantic pigtoe) cannot pass through them. This leads to loss of access to quality habitat, as well as fragmented habitat and a loss of connectivity between populations. This can limit both genetic exchange and recolonization opportunities.

All of the river basins within the range of this species are affected to some extent by development, ranging from 3 percent of the Black River subbasin in the Cape Fear River Basin to 70 percent of the Crabtree Creek subbasin in the Neuse River Basin (based on the 2011 National Land Cover Data). The Neuse River basin in North Carolina contains one-sixth of the entire State's population, indicating heavy development pressure on the watershed. As another example, the Middle James MU (in the James population) contains 159 impaired stream miles (*i.e.,* waters that exceed water quality standards for a particular parameter), 2 major discharges, 32 minor discharges, and over 1,300 road crossings. Similarly, the Muddy Creek MU is currently made up of 12.3 percent impervious surfaces. For complete data on all of the populations, refer to appendix C of the SSA report.

Agricultural Practices: The main impacts to the Atlantic pigtoe from agricultural practices are from nutrient pollution and water pumping for irrigation. Fertilizers and animal manure, which are both rich in nitrogen and phosphorus, are the primary sources of nutrient pollution from agricultural sources when agricultural best management practices are not used. Excess nutrients impact water quality when it rains or when water and soil containing nitrogen and phosphorus wash into nearby waters or leach into the water table and ground waters causing algal blooms. These algal blooms can harm freshwater mussels by suffocating host fish and decreasing available oxygen in the water column.

It is common practice to pump water for irrigation from adjacent streams or rivers into a reservoir pond, or to spray the stream or river water directly onto crops. If the water withdrawal is excessive or done illegally, this may cause impacts to the amount of water available to downstream sensitive areas during low flow months, resulting in dewatering of channels and stranding of mussels, leading to desiccation and death. The Cape Fear River basin has 33 reservoirs, many of them supplying water to some of the most populated areas in North Carolina, including the Triad (Greensboro and High Point), Chapel Hill, Fayetteville, and Wilmington. All told, this basin contains one-fifth of the entire State's population and is the most industrialized basin, as well as home to the most large-scale livestock operations in the State. However, according to the 2011 National Land Cover Data, all of the watersheds within the range of the Atlantic pigtoe are affected by agricultural land uses, most with 20 percent or more of the watershed having been converted to agricultural use.

Incompatible Forest Management: Silvicultural activities, when performed according to strict forest practices guidelines (FPGs) or BMPs, can retain adequate conditions for aquatic ecosystems; however, when FPGs/BMPs are not followed or are implemented poorly, these practices can also contribute to the myriad of stressors facing aquatic systems in the Southeast. Both small- and large-scale clearing of forests have been shown to have a significant impact upon the physical, chemical, and biological characteristics of adjacent small streams (Allan 1995, pp. 324–327; Valente-Neto 2015, p. 116). Clearcutting and harvests in riparian systems can eliminate shade provided by forest canopies, exposing streams to more sunlight and increasing the instream water temperature (Swift and Messer 1971, p. 111; Hewlett and Forston 1982, p. 983; GB Rishel 1982, p. 112; Lynch et al. 1984, p. 161; Allan 1995, p. 325; Keim and Shoenholtz 1999, p. 197; Carroll et al. 2004, p. 275; B.D. Clinton 2011, p. 979; Caldwell et al. 2014, p. 3). The increase in stream temperature and light after deforestation of riparian areas alters the macroinvertebrate and other aquatic species richness and abundance composition in streams (Wenger 1999, p. 35; Caldwell et al. 2014, p. 3). As

stated above, the Atlantic pigtoe is sensitive to changes in temperature, and sustained temperature increases will stress and possibly lead to mortality for this species.

Forestry activities can include the construction of logging roads through the riparian zone, and this can directly degrade nearby stream environments. Roads can cause point-source pollution and sedimentation, as well as sediment traveling downstream into sensitive habitats. These effects lead to stress and mortality for the species, as discussed under *Development,* above, and as reported in studies of forestry-related sedimentation effects on survival of aquatic invertebrates (Osterling et al. 2008, pp. 1368–1369; Reid et al. 2013, pp. 571, 577; O'Driscoll et al. 2014, pp. 87–90; Osterling and Hogberg 2014, pp. 215–217, 219; Osterling 2015, pp. 448–450; Osterling 2019, pp. 444, 446–448). While BMPs are widely adhered to now, they were not historically a common practice, and implementation is still imperfect. The most recent surveys of BMP implementation rates in North Carolina show that they average approximately 83–90 percent in river basins where Atlantic pigtoe occurs (Coats 2017, p. 38), and in Virginia, the most recent average Statewide BMP implementation rate was 91.8 percent (VDOF 2020, p. 2). Accordingly, while incompatible implementation is rare, the failure to implement BMPs or inadequate implementation can have negative effects on sensitive aquatic species. Acute impacts associated with episodic events may be particularly consequential for long-lived, sedentary species like the Atlantic pigtoe. Further, the most recent assessment of forestry BMPs in North Carolina reported that improperly implemented BMPs associated with SMZs and stream crossings were among the most frequently associated with risks to water quality (Coats 2017, p. 9); VDOF similarly identified stream crossings, along with roads and skid trails, among the BMP categories frequently associated with water quality concerns (VDOF 2020, p. 3).

Systemic Changes

Climate Change: Aquatic systems are encountering changes and shifts in seasonal patterns of precipitation and runoff as a result of climate change. While mussels evolved in habitats that experience seasonal fluctuations in discharge, global weather patterns can have an impact on the normal regimes (*e.g.,* El Niño or La Niña). Both excessively high (*i.e.,* floods and storms) and excessively low (*i.e.,* droughts) flows can adversely affect the species.

As to droughts, even naturally occurring low flow events can cause mussels to become stressed, either because they must exert significant energy to move to deeper waters or they may succumb to desiccation. Because late summer and early fall are stressful periods for the species due to low flows, droughts during this time of year can be especially harmful, resulting in increased mortality rates. Atlantic pigtoe habitat must have adequate flow to deliver oxygen, enable passive reproduction, and deliver food to filter-feeding mussels. Further, flow removes contaminants and fine sediments from interstitial spaces, preventing mussel suffocation. Droughts have impacted all river basins within the range of Atlantic pigtoe, from an ''abnormally dry'' ranking for North Carolina and Virginia in 2001 on the Southeast Drought Monitor scale to the highest ranking of ''exceptionally dry'' for the entire range of the species in 2002 and 2007. In 2015, the entire Southeast ranged from ''abnormally dry'' to ''moderate drought'' or ''severe drought.'' These data covered the first week in September, which, as noted above, is a very sensitive time for drought to be affecting the species. The Middle Neuse tributaries of the Neuse River basin had consecutive drought years from 2005 through 2012, indicating sustained stress on the species over a long period of time.

Increases in the frequency and strength of storms events alter stream habitat. Stream habitat is altered either directly via channelization or clearing of riparian areas, or indirectly via high stream flows that reshape the channel and cause sediment erosion. The large volumes and velocity of water, combined with the extra debris and sediment entering streams following a storm, stress, displace, or kill Atlantic pigtoes and the host fish species on which they depend.

Sedentary freshwater mussels have limited ability to seek refuge from droughts and floods, and they are completely dependent on specific water temperatures to complete their physiological requirements. Changes in water temperature lead to stress, increased mortality, and also increase the likelihood of extinction.

Invasive Species: Nonnative species are invading aquatic communities and altering biodiversity by competing with native species for food, light, or breeding and nesting areas in many areas across the range of the Atlantic pigtoe. For example, the Asian clam (*Corbicula fluminea*) alters benthic substrates, competes with native species for limited resources, and causes ammonia spikes in surrounding water when they die off en masse. Native mussel growth is negatively associated with Asian clam abundance, indicating invasive clams may be a pervasive stressor to native species (Haag et al. 2021, pp. 451–454). Juvenile mussels need low levels of ammonia to survive, and freshwater mollusks are more sensitive than previously known to some chemical pollutants, including ammonia (Augspurger et al. 2003, entire and references therein). The Asian clam is ubiquitous across the southeastern United States and is present in watersheds across the range of the Atlantic pigtoe.

The flathead catfish (*Pylodictis olivaris*) is an apex predator that feeds on almost anything, including other fish, crustaceans, and mollusks. Predation by flathead catfish diminishes host fish communities, reducing the amount of fish available as hosts for the mussels to complete their glochidia life stage. Introductions of flathead catfish into rivers in North Carolina and Georgia have led to steep declines in numbers of native fish (Service 2021, p. 59). The flathead catfish has been documented in six of the seven river systems currently inhabited by the Atlantic pigtoe (James, Roanoke, Tar, Neuse, Cape Fear, and Yadkin-Pee Dee).

Hydrilla (*Hydrilla verticillata*), an aquatic plant, alters habitat, decreases flows, and contributes to sediment buildup in streams. Hydrilla occurs in several watersheds where the Atlantic pigtoe occurs, including recent documentation from the upper Neuse system and the Tar River. The dense growth is altering the flow in these systems and causing sediment buildup, which can cause suffocation in filter-feeding mussels. While data are lacking on hydrilla currently having population-level effects on the Atlantic pigtoe, the spread of this invasive plant is expected to increase in the future.

Dams and Barriers: Extinction and extirpation of North American freshwater mussels can be traced to impoundment and inundation of riffle habitats in all major river basins of the central and eastern United States. Upstream of dams, the change from flowing to impounded waters, increased depths, increased buildup of sediments, decreased dissolved oxygen, and the drastic alteration in resident fish populations can threaten the survival of mussels and their overall reproductive success. Downstream of dams, fluctuations in flow regimes, minimal releases and scouring flows, seasonal dissolved oxygen depletion, reduced or increased water temperatures, and changes in fish assemblages can also

threaten the survival and reproduction of many mussel species.

Because Atlantic pigtoes use smaller host fish (*e.g.,* darters and minnows), they are even more susceptible to impacts from habitat fragmentation due to increasing distance between suitable habitat patches and a low likelihood of host fish swimming over that distance. Even improperly constructed culverts at stream crossings can act as significant barriers and have some similar effects as dams on stream systems (see discussion under *Development,* above). These barriers not only fragment habitats along a stream course, they also contribute to genetic isolation of the Atlantic pigtoe. Nearly all of the MUs containing Atlantic pigtoe populations have been impacted by dams, with as few as 2 dams in Mill Creek in the James River basin to 237 dams throughout the Middle Neuse basin (Service 2021, appendix D). The Middle Neuse also contains over 5,000 stream crossings, so connectivity in that basin has been severely affected by barriers. Only the Edisto River basin within the range of the Atlantic pigtoe has not been impacted by dams.

Regulatory Mechanisms

State Endangered Species Laws

Each state within the range of the Atlantic Pigtoe has state-level legislation modeled after the federal Endangered Species Act: In Virginia it is both the Virginia Endangered Species Act and the Endangered Plant and Insect Species Act, in North Carolina it is the North Carolina Endangered Species Act, in South Carolina it is the Nongame and Endangered Species Conservation Act, and in Georgia it is the Endangered Wildlife Act. Animal species that are protected by the state laws are regulated by state wildlife agencies: The Virginia Department of Game and Inland Fisheries, the North Carolina Wildlife Resources Commission, the South Carolina Department of Natural Resources, and the Georgia Department of Natural Resources.

The state endangered species protection laws allow the state wildlife agencies to identify, document, and protect any animal species that is considered rare or in danger of extinction. In most of the states (VA, NC, SC, GA), illegal activities include take, transport, export, processing, selling, offering for sale, or shipping species, and the penalty for doing so is a misdemeanor crime, usually resulting in a fine of no more than $1,000 or imprisonment not to exceed a year (Pellerito 2002, entire). There are no mechanisms for recovery, consultation, or critical habitat designation other than in North Carolina where conservation plans must be developed for all state listed species (Pellerito 2002, Snape and George 2010, p.346). In addition, nothing in the North Carolina Endangered Species Act ''shall be construed to limit the rights of a landholder in the management of his lands for agriculture, forestry, development, or any other lawful purpose'' (NC GS 113–332).

State and Federal Stream Protections (Buffers & Permits)

A buffer is a strip of trees, plants, or grass along a stream or wetland that naturally filters out dirt and pollution from rain water runoff before it enters rivers, streams, wetlands, and marshes (SELC 2014, p.2). Several state laws require setbacks or buffers, and all allow variances/waivers for those restrictions. Virginia's Chesapeake Bay Preservation Act requires 100-foot buffers on all perennial streams in designated ''Resource Protection Areas.'' North Carolina used to have buffer requirements in specific watersheds (*e.g.,* Tar-Pamlico, Neuse, Catawba, Jordan Lake, and Goose Creek), however, the NC Legislature enacted a Regulatory Reform effort, including ''Riparian Buffer Reform'' that allowed for the amendment of the buffer rules to allow/exempt development (see Session Law 2012–200, Section 8 and Session Law 2015–246, Section 13.1, G.S. 143–214.23A (NCDEQ 2016, entire)). North Carolina also has guidance for 200 foot riparian buffer protections for streams draining to listed aquatic species habitats (NCWRC 2002, p.11). In South Carolina, 30–45 ft buffer management zones are required for stormwater management (SCDHEC 2016, entire). In Georgia, all state waters are protected by a 25-foot vegetated buffer, and trout waters have a 50-foot vegetated buffer requirement.

Section 401 of the federal Clean Water Act (CWA) requires that an applicant for a federal license or permit provide a certification that any discharges from the facility will not degrade water quality or violate water-quality standards, including state-established water quality standard requirements. Section 404 of the CWA establishes a program to regulate the discharge of dredged and fill material into waters of the United States. Permits to fill wetlands and fill, culvert, bridge or re-align streams or water features are issued by the U.S. Army Corps of Engineers under Nationwide, Regional General Permits or Individual Permits.

- Nationwide Permits are for ''minor'' impacts to streams and wetlands, and do not require an intense review process. These impacts usually include stream impacts under 150 feet, and wetland fill projects up to 0.50 acres. Mitigation is usually provided for the same type of wetland or stream impacted, and is usually at a 2:1 ratio to offset losses and make the ''no net loss'' closer to reality.
- Regional General Permits are for various specific types of impacts that are common to a particular region; these permits will vary based on location in a certain region/state.
- Individual permits are for the larger, higher impact and more complex projects. These require a complex permit process with multi-agency input and involvement. Impacts in these types of permits are reviewed individually and the compensatory mitigation chosen may vary depending on project and types of impacts.

State and Federal Water Quality Programs

Current State regulations regarding pollutants are designed to be protective of aquatic organisms; however, freshwater mollusks may be more susceptible to some pollutants than the test organisms commonly used in bioassays. Additionally, water quality criteria may not incorporate data available for freshwater mussels (March et al. 2007, pp. 2,066–2,067). A multitude of bioassays conducted on 16 mussel species (summarized by Augspurger et al. 2007, pp. 2025–2028) show that freshwater mollusks are more sensitive than previously known to some chemical pollutants, including chlorine, ammonia, copper, fungicides, and herbicide surfactants. Another study found that nickel and chlorine were toxic to a federally threatened mussel species at levels below the current criteria (Gibson 2015, pp. 90–91). The study also found mussels are sensitive to SDS (sodium dodecyl sulfate), a surfactant commonly used in household detergents, for which water quality criteria do not currently exist. Several studies have demonstrated that the criteria for ammonia developed by EPA in 1999 were not protective of freshwater mussels (Augspurger et al. 2003, p. 2,571; Newton et al. 2003, pp. 2,559–2,560; Mummert et al. 2003, pp. 2,548–2,552). However, in 2013 EPA revised its recommended criteria for ammonia. The new criteria are more stringent and reflect new toxicity data on sensitive freshwater mollusks (78 FR 52192, August 22, 2013; p. 2). All of the states in the range of the Atlantic Pigtoe have not yet adopted the new ammonia criteria. NPDES permits are valid for 5 years, so even after the new criteria are

adopted, it could take several years before facilities must comply with the new limits.

TMDL, or Total Maximum Daily Load, is a regulatory term from the CWA describing a plan for restoring impaired waters that identify the maximum amount of a pollutant that a body of water can receive while still maintaining water quality standards. In North Carolina, despite management actions that started in the mid-1990s, long term monitoring and trend analyses have demonstrated that TMDL goals have not been met: ''Despite the fact that the targeted point and nonpoint pollution sources have been able to meet their nutrient reductions, total nitrogen and total phosphorous concentrations do not show a downward trend and loads have not permanently fallen below 1991 baseline load goals'' (as referenced (p.6) in SRI public comment letter on Yellow Lance Listing to USFWS, 6/5/2017).

Under the CWA, states are required to review their water quality standards and classifications every three years to make any modifications necessary to protect the waters of the state (NCDEQ 2016, entire). During this process, known as the Triennial Review, state water quality staff review current EPA guidelines, scientific data, and public comments and make recommendations for any changes of the water quality standards. In North Carolina, the most recent triennial review started in 2007 and was not completed until 2015 (NCDEQ 2016, entire). The state of North Carolina has not addressed water quality standards for several pollutants of concern for freshwater mussles, particularly ammonia, despite the EPA's 2013 recommended ambient water quality criteria for ammonia (as referenced (p.7) in SRI public comment letter on Yellow Lance Listing to USFWS, 6/5/2017).

In summary, despite existing authorities such as the Clean Water Act, pollutants continue to impair the water quality throughout the current range of the Atlantic Pigtoe. State and Federal regulatory mechanisms have helped reduce the negative effects of point source discharges since the 1970s, yet these regulations are difficult to implement and regulate. While new water quality criteria are being developed that take into account more sensitive aquatic species, most criteria currently do not. It is expected that several years will be needed to implement new water quality criteria throughout the range.

Synergistic Effects

In addition to impacting the species individually, it is likely that several of the above-summarized risk factors are acting synergistically or additively on the species. The combined impact of multiple stressors is likely more harmful than a single stressor acting alone. For example, in the Meherrin River MU, there are four stream reaches with 34 miles of impaired streams. They have low benthic-macroinvertebrate scores, low dissolved oxygen, low pH, and contain *Escherichia coli* (also known as *E. coli*). There are 16 non-major and 2 major discharges within this MU, along with 7 dams, and 676 road crossings. Additionally, droughts were recorded for 4 consecutive years (2007–2010) in this MU. The combination of all of these stressors on the sensitive aquatic species in this habitat has probably impacted Atlantic pigtoe, in that only two individuals have been recorded here since 2005, and therefore are affecting the species more severely in combination than any factor alone.

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have not only analyzed individual effects on the species, but we have also analyzed their potential cumulative effects. We incorporate the cumulative effects into our SSA analysis when we characterize the current and future condition of the species. To assess the current and future condition of the species, we undertake an iterative analysis that encompasses and incorporates the threats individually and then accumulates and evaluates the effects of all the factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative effects analysis.

Conservation Actions

The Service and State wildlife agencies are working with numerous partners to provide technical guidance and offering conservation tools to meet both species and habitat needs in aquatic systems in North Carolina. Land trusts are targeting key parcels for acquisition; Federal and State biologists are surveying and monitoring species occurrences; and, recently, there has been a concerted effort to ramp up captive propagation and species population restoration via augmentation, expansion, and reintroduction efforts. In 2014, NCWRC staff and partners began a concerted effort to propagate the Atlantic pigtoe in hopes of augmenting existing populations in the Tar and Neuse River basins. In July 2015, 250 Atlantic pigtoes were stocked into Sandy Creek, a tributary of the Tar River. Annual monitoring to evaluate growth and survival is planned, and additional propagation and stocking efforts will continue in upcoming years (Service 2021, p. 59).

Current Condition of Atlantic Pigtoe

The historical range of the Atlantic pigtoe included 12 populations in Atlantic river basins from Virginia to Georgia. The surveys conducted from 2005 to 2018 indicate that the currently occupied range of the Atlantic pigtoe consists of 13 MUs within 7 populations in Virginia and North Carolina, in the Tar, Neuse, James, Chowan, Roanoke, Cape Fear, and Yadkin-Pee Dee River basins. The species is presumed extirpated from the southern portion of its range, including the Catawba, Edisto, Savannah, Ogeechee, and Altamaha River basins. The Atlantic pigtoe currently (defined as the observation of at least one specimen from 2005 to 2019) occupies 13 of the 81 historically occupied MUs. At the population level, the overall current condition (= resiliency) of the extant populations was estimated to be high for the Tar Population; moderate for the Neuse Population; and low for the James, Chowan, Roanoke, Cape Fear, and Yadkin-Pee Dee populations.

The Atlantic pigtoe currently has reduced adaptive potential due to limited representation (compared with historical representation) in seven river basins and three physiographic regions. The species retains 58 percent of its known river basin variability, but, as discussed above, distribution has been reduced in the James, Chowan, Roanoke, Cape Fear, and Yadkin-Pee Dee populations. In addition, although the species continues to maintain physiographic representation in all three regions it historically occupied, occupancy has decreased in each region. A 67 percent estimated loss has occurred in the Mountain region's watersheds, 48 percent loss in the Piedmont region's watersheds, and 76 percent loss in the Coastal Plain region's watersheds. Latitudinal variability is also reduced and is largely limited to the central portions of its historical range, primarily in the Tar and Neuse basins.

Redundancy was estimated as the number of historically occupied MUs that remain currently occupied. The species has limited redundancy within the James, Chowan, Roanoke, and Cape Fear River populations, and only two

populations (Tar and Neuse) have multiple moderate or highly resilient MUs. Overall, the species has decreased redundancy across its range due to an estimated 60 percent reduction in occupancy compared to historical levels.

Future Scenarios

For the purpose of this assessment, we define viability as the ability of the species to sustain populations in the wild over time. To help address uncertainty associated with the degree and extent of potential future stressors and their impacts on the needs of the species, the 3 Rs were applied using four plausible future scenarios. We devised these scenarios by eliciting expert information on the primary stressors anticipated to affect the species into the future: Habitat loss and degradation due to urbanization and the effects of climate change. The models that were used to forecast both urbanization and climate change projected 50 years in the future. Synergistic interactions are possible between the effects of climate change and the effects of other potential threats, such as development. Increases in temperature and changes in precipitation are likely to affect stream dynamics, which will in turn affect the Atlantic pigtoe. However, it is difficult to project how climate change will affect stream dynamics because there can be both an increase in storm events as well as an increase in low flow, or drought, conditions. Uncertainty about how stream dynamics will respond to climate change, combined with uncertainty about how changes in instream habitat conditions would affect suitability for Atlantic pigtoe, make projecting possible synergistic effects of climate change on the Atlantic pigtoe too speculative. Below, we provide a brief summary of each plausible future scenario (see Table 1); for more detailed information on these models and their projections, please see the SSA report (Service 2021, chapter 3).

Under Scenario 1, the ''Status Quo'', factors that influence current populations of Atlantic pigtoe were assumed to remain constant over the 50 year time horizon. Under this scenario a loss of resiliency, representation, and redundancy is expected. Under this scenario, we predicted that no MUs would remain in high condition, 2 would be in moderate condition, 6 would be in low condition, and 20 MUs would be likely extirpated. Redundancy would be reduced to two MUs in the Tar Population. Representation would also be reduced, primarily with reduced variability in the Mountains and Coastal Plain.

Under scenario 2, the ''Pessimistic'', factors that negatively influence Atlantic pigtoe populations get worse. We predicted substantial losses of resiliency, representation, and redundancy. Redundancy would be reduced to 4 MUs in just two populations, and the resiliency of those populations is expected to be low; 24 MUs were predicted to be extirpated. All measures of representation are predicted to decline under this scenario, leaving remaining Atlantic pigtoe populations underrepresented in river basin and physiographic variability.

Under scenario 3, the ''Optimistic'', factors that influence the habitat conditions where Atlantic pigtoe populations exist were predicted to slightly improve over the 50 year time horizon. We predicted slightly higher levels of resiliency, representation, and redundancy than were estimated under the Status Quo or Pessimistic options. Two MUs would be in high condition, 5 in moderate condition, and 5 would be in low condition, but 16 would remain extirpated. Despite predictions of population persistence in the Chowan and Pee Dee river basins, these populations are expected to retain only low levels of resiliency; thus, levels of representation are also predicted to decline under this scenario.

Finally, under scenario 4, the ''Opportunistic'', landscape-level factors that influence populations of Atlantic pigtoe were predicted to get moderately worse. We predicted reduced levels of resiliency, representation, and redundancy. None of the MUs would be in high condition, 3 would be in moderate condition, 5 would be in low condition, and 20 would be likely extirpated. Redundancy would be reduced by losing 6 MUs compared to current condition. Under the ''Opportunistic'' scenario, representation is predicted to be reduced, with only 6 (50 percent) of the former 12 occupied river basins remaining occupied and with reduced variability in all three physiographic regions. This expected reduction in both the number and distribution of resilient populations is likely to make the species vulnerable to catastrophic disturbance.

BILLING CODE 4333–15–P

BILLING CODE 4333–15–C

Table 1. Current and Future Scenario Summary for Atlantic Pigtoe.

POPULATIONS: Management Units	Future Scenarios of Population Conditions				
	Current	**Status Quo**	**Pessimistic**	**Optimistic**	**Opportunistic**
James: Craig Creek Subbasin	Moderate	Low	Likely Extirpated	Moderate	Moderate
James: Mill Creek	Presumed Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
James: Rivanna	Presumed Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
James: Upper James	Presumed Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
James: Middle James	Very Low	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
James: Appomattox	Presumed Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
Chowan: Nottoway	Moderate	Likely Extirpated	Likely Extirpated	Low	Low
Chowan: Meherrin	Low	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
Roanoke: Dan River Subbasin	Low	Likely Extirpated	Likely Extirpated	Moderate	Likely Extirpated
Roanoke: Roanoke	Presumed Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
Tar: Upper/Middle Tar	High	Low	Low	Moderate	Low
Tar: Lower Tar	Low	Low	Likely Extirpated	Low	Likely Extirpated
Tar: Fishing Ck	High	Moderate	Low	High	Moderate
Tar: Sandy-Swift	High	Moderate	Low	High	Moderate
Neuse: Upper Neuse	Moderate	Low	Likely Extirpated	Moderate	Low
Neuse: Middle Neuse	Moderate	Likely Extirpated	Likely Extirpated	Low	Likely Extirpated
Cape Fear: New Hope	Moderate	Low	Likely Extirpated	Low	Likely Extirpated
Cape Fear: Deep River Subbasin	Low	Likely Extirpated	Likely Extirpated	Moderate	Low
Cape Fear: Mainstem	Presumed Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
Cape Fear: Black	Presumed Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
Pee Dee: Muddy	Presumed Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
Pee Dee: Uwharrie/Little	Low	Low	Low	Low	Low
Pee Dee: Goose/Lanes	Presumed Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
Catawba	Presumed Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
Edisto	Presumed Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
Savannah	Presumed Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
Ogeechee	Presumed Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated
Altamaha	Presumed Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated

Determination of the Atlantic Pigtoe's Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an ''endangered species'' or a ''threatened species.'' The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of endangered species or threatened species because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) Overutilization for commercial, recreational, scientific, or educational purposes; (C) Disease or predation; (D) The inadequacy of existing regulatory mechanisms; or (E) Other natural or manmade factors affecting its continued existence.

Atlantic Pigtoe's Status Throughout All of Its Range

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Atlantic pigtoe. Currently the Atlantic pigtoe is presumed extirpated from 54 percent (15) of the historically occupied MUs; of the remaining currently extant populations (13 MUs), 57 percent are characterized as moderately or highly resilient, and 43 percent are currently characterized by low resiliency. Many of the streams that remain part of the current species' range are estimated to be in low or very low condition with decreased occupancy of Atlantic pigtoe.

The Atlantic pigtoe faces threats from declines in water quality, loss of stream flow, riparian and instream fragmentation, and deterioration of instream habitats (Factor A). These threats, which are expected to be exacerbated by continued urbanization (Factor A) and effects of climate change (Factor E), will impact the future viability of the Atlantic pigtoe. We did not find that the Atlantic pigtoe was impacted by overutilization (Factor B), or by disease or predation (Factor C). While there are regulatory mechanisms in place that may benefit the Atlantic pigtoe, the existing regulatory mechanisms did not reduce the impact of the stressors to the point that the species is not at risk of extinction (Factor D).

Given current and future decreases in resiliency, populations become more vulnerable to extirpation from stochastic events, in turn, resulting in concurrent losses in representation and redundancy. The range of plausible future scenarios of Atlantic pigtoe habitat conditions and population factors suggest reduced viability into the future.

We considered whether the Atlantic pigtoe is currently in danger of extinction and determined that endangered status is not appropriate. Notwithstanding the number of populations that are no longer extant, several moderately resilient populations remain over portions of the species' historical range. The historical range of the Atlantic pigtoe included streams and rivers in 12 Atlantic Slope drainages from the James River Basin to the Altamaha River Basin, with the documented historical distribution in 28 MUs within those basins. Currently, the Atlantic pigtoe is presumed extirpated from 54 percent (15) of the historically occupied MUs and 5 of the drainages. Of the remaining 13 occupied MUs, 3 (21 percent) are estimated to be highly resilient and 5 (36 percent) moderately resilient, with 5 (43 percent) having low resiliency. Eight moderate to high resiliency MUs provide the ability for the species to withstand stochastic disturbance events. Scaling up from the MU to the population level, 1 of 12 former populations (the Tar population) was estimated to have high resiliency, 1 population (the Neuse population) was estimated to have moderate resiliency, 5 populations (the James, Chowan, Roanoke, Cape Fear, and Yadkin-Pee Dee populations) had low estimated resiliency, and 5 of the former 12 populations are presumed extirpated; this means that 42 percent of the species' historical range has been eliminated. Seventy-one percent of streams that remain part of the current species' range are estimated to be in low condition as defined in the SSA report. The species continues to maintain physiographic representation in all 3 regions it historically occupied, although occupancy has decreased in each region by between 48 and 76 percent. However, while threats are currently acting on the species and many of those threats are expected to continue into the future (see below), we did not find that the species is currently in danger of extinction throughout all of its range. With eight moderately or highly resilient MUs in three physiographic regions, the current condition of the species still provides resiliency, redundancy, and representation such that it is not at risk of extinction now.

However, after evaluating threats to the species and assessing the cumulative effect of the threats under the Act's section 4(a)(1) factors, we predict that the population and habitat factors that we used to determine the resiliency, representation, and redundancy for the Atlantic pigtoe will continue to decline. Fifty years was considered ''foreseeable'' in this case because it included projections from both available models, and Atlantic pigtoes are a long-lived and slow-growing species. We can reliably predict both the future threats and the species' responses to those threats over 50 years as presented in the models of predicted urbanization and climate change.

As discussed above, the range of plausible future scenarios of Atlantic pigtoe habitat conditions and population factors projects reduced viability into the future. Under all future scenarios, resiliency is low in a majority of the remaining populations, and many populations are likely extirpated so that redundancy and representation are predicted to be significantly reduced. This expected reduction in both the number and distribution of sufficiently resilient populations is likely to make the species vulnerable to catastrophic disturbance. Our analysis of the species' future conditions show that habitat modification and destruction (Factor A) and other natural and manmade factors (Factor E) will continue to impact the resiliency, representation, and redundancy for the Atlantic pigtoe so that it is likely to become in danger of extinction throughout all or a significant portion of its range within the foreseeable future.

Atlantic Pigtoe's Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. The court in *Center for Biological Diversity* v. *Everson,* 2020 WL 437289 (D.D.C. Jan. 28, 2020) (*Center for Biological Diversity*), vacated the aspect of the Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37578; July 1, 2014) that provided that the Service does not undertake an analysis of significant portions of a species' range if the species warrants listing as threatened throughout all of its range. Therefore,

we proceed to evaluate whether the species is endangered in any significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant; and (2) the species is in danger of extinction in that portion. Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status'' question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

Following the court's holding in *Center for Biological Diversity,* we now consider whether there are any significant portions of the species' range where the species is in danger of extinction now (*i.e.,* endangered). In undertaking this analysis for the Atlantic pigtoe, we chose to address the status question first—we considered information pertaining to the geographic distribution of both the species and the threats that the species faces to identify any portions of the range where the species is endangered.

Specifically, we considered whether the threats are geographically concentrated in any portion of the species' range at a biologically meaningful scale. We examined the following threats: Declines in water quality, loss of stream flow, riparian and instream fragmentation, and deterioration of instream habitats, including cumulative effects. Overall, we found that threats are likely acting on individuals or MUs, or even basins (populations), similarly across the species' range. These threats are certain to occur, and in those basins with MUs that are predominantly in low condition currently, the populations are facing the same threats as those in moderate or high resiliency condition.

Thus, there are no portions of the species' range where the species has a different status from its rangewide status. Therefore, no portion of the species' range provides a basis for determining that the species is in danger of extinction in a significant portion of its range, and we determine that the species is likely to become in danger of extinction within the foreseeable future throughout all of its range. This is consistent with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Determination of Status

Our review of the best available scientific and commercial information indicates that the Atlantic pigtoe meets the Act's definition of a threatened species. Therefore, we are listing the Atlantic pigtoe as a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act requires the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed and preparation of a draft and final recovery plan. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan identifies recovery criteria for review of when a species may be ready for for removal from protected status (''delisting''), and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our website (*http://www.fws.gov/endangered*) or from our Raleigh Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

Following publication of this rule, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the States of Virginia, North Carolina, South Carolina, and Georgia will be eligible for Federal funds to implement management actions that promote the protection or recovery of the Atlantic pigtoe. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Please let us know if you are interested in participating in recovery efforts for the Atlantic pigtoe. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(2) of the Act requires Federal

agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of any endangered or threatened species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph may include, but are not limited to, management and any other landscape-altering activities on Federal lands administered by the Service, U.S. Forest Service, and National Park Service; issuance of section 404 Clean Water Act (33 U.S.C. 1251 *et seq.*) permits by the U.S. Army Corps of Engineers; and construction and maintenance of roads or highways by the Federal Highway Administration.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a listing on proposed and ongoing activities within the range of the listed species. The discussion below regarding protective regulations under section 4(d) of the Act complies with our policy.

II. Final Rule Issued Under Section 4(d) of the Act

Background

Section 4(d) of the Act contains two sentences. The first sentence states that the Secretary shall issue such regulations as she deems necessary and advisable to provide for the conservation of species listed as threatened. The U.S. Supreme Court has noted that statutory language like ''necessary and advisable'' demonstrates a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592 (1988)). Conservation is defined in the Act to mean the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Additionally, the second sentence of section 4(d) of the Act states that the Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants. Thus, the combination of the two sentences of section 4(d) provides the Secretary with wide latitude of discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of the threatened species. The second sentence grants particularly broad discretion to the Service when adopting the prohibitions under section 9.

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a species. For example, courts have upheld rules developed under section 4(d) as a valid exercise of agency authority where they prohibited take of threatened wildlife, or include a limited taking prohibition (see *Alsea Valley Alliance* v. *Lautenbacher,* 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council* v. *National Marine Fisheries Service,* 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002)). Courts have also upheld 4(d) rules that do not address all of the threats a species faces (see *State of Louisiana* v. *Verity,* 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, ''once an animal is on the threatened list, the Secretary has an almost infinite number of options available to [her] with regard to the permitted activities for those species. [She] may, for example, permit taking, but not importation of such species, or [s]he may choose to forbid both taking and importation but allow the transportation of such species'' (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Exercising its authority under section 4(d), the Service has developed a rule that is designed to address the Atlantic pigtoe's specific threats and conservation needs. Although the statute does not require us to make a ''necessary and advisable'' finding with respect to the adoption of specific prohibitions under section 9, we find that this rule as a whole satisfies the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the Atlantic pigtoe. As discussed above under Summary of Biological Status and Threats, we have concluded that the Atlantic pigtoe is likely to become in danger of extinction within the foreseeable future primarily due to habitat degradation from stressors influencing water quality, water quantity, instream habitat, and habitat connectivity. The provisions of this 4(d) rule will promote conservation of the Atlantic pigtoe by encouraging management of the landscape in ways that meet both land management considerations and the conservation needs of the Atlantic pigtoe. The provisions of this rule are one of many tools that the Service will use to promote the conservation of the Atlantic pigtoe.

Provisions of the 4(d) Rule

This 4(d) rule will provide for the conservation of the Atlantic pigtoe by prohibiting the following activities, except as otherwise authorized or permitted: Importing or exporting; take; possession and other acts with unlawfully taken specimens; delivering, receiving, transporting, or shipping in interstate or foreign commerce in the course of commercial activity; or selling or offering for sale in interstate or foreign commerce.

Import/export, possession, transportation, sale, and commerce are of concern for many aquatic mollusks, primarily because they are sought after for use as fishing bait and for human consumption. Regulating these activities will help protect the Atlantic pigtoe from exploitation.

Under the Act, ''take'' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Some of these provisions have been further defined in regulation at 50 CFR 17.3. Take can occur knowingly or otherwise, by direct and indirect impacts, and intentionally or incidentally. Protecting the Atlantic pigtoe from direct forms of take, such as physical injury or killing or unauthorized handling or collecting of the species, whether incidental or intentional, will help preserve and recover the species. Therefore, we prohibit intentional take of Atlantic pigtoe, including, but not limited to, capturing, handling, trapping, collecting, or other activities.

Also, as discussed above under Summary of Biological Status and Threats, habitat degradation from stressors influencing water quality, water quantity, instream habitat, and habitat connectivity are affecting the status of the Atlantic pigtoe. Across the species' range, stream and water quality have been degraded physically by sedimentation, pollution, contaminants, impoundments, channelization, destruction of riparian habitat, and loss of riparian vegetation due to development, agricultural practices, land conversion, incompatible forest management, invasive species, and dams and barriers. Other habitat or hydrological alteration (such as ditching, draining, diverting, dredging, snagging, impounding, channelization, or modification of stream channels or

banks; discharge of fill material into stream channels; or diversion or alteration of surface or ground water flow into or out of a stream) will impact the habitat of the species. Regulating incidental take that may result from these activities will help preserve the species' remaining populations, slow their rate of decline, and decrease synergistic, negative effects from other threats. Therefore, we prohibit incidental take of the Atlantic pigtoe resulting from activities that destroy, alter, or degrade the habitat in the manner described above.

As discussed above, during both of the public comment periods, the Service received numerous comments on its proposal to exempt from these prohibitions incidental take resulting from silvicultural practices and forest management activities (see Summary of Comments and Recommendations, above). Forestry BMPs, when properly implemented, protect water quality and help conserve aquatic species, including the Atlantic pigtoe. Forest landowners who properly implement those BMPs are helping conserve the pigtoe, and this 4(d) rule is an incentive for all landowners to properly implement BMPs to avoid any take implications. Further, those forest landowners who are third-party certified to a credible forest management standard are providing audited certainty that BMP implementation is taking place across the landscape.

To address any uncertainty regarding which silvicultural and forest management BMPs will satisfy the 4(d) rule's exception for incidental take resulting from silvicultural practices and forest management activities, our regulations specify the conditions that must be met. Further, we revised our 4(d) rule language to clarify that to qualify for the exception, the BMPs must result in protection of the habitat features that provide for the breeding, feeding, sheltering, and dispersal needs of the Atlantic pigtoe, which will in turn provide for the conservation of the species. In waterbodies that support listed aquatic species, a wider SMZ is more effective at reducing sedimentation, maintaining lower water temperatures through shading, and introducing food (such as leaves and insects) into the food chain (VDOF 2011, p. 37). Ninety percent of the food in forested streams comes from bordering vegetation (NCWRC 2002, p. 6; Service 2006, p. 6; Stewart et al. 2000, p. 210; Service 2021, p. 11). Atlantic pigtoes require cool, well-oxygenated water, and a clean stream bottom (Service 2021, p. 11). A lack of these features limits the number of pigtoes a stream can support. Aquatic habitat and suitable water temperature can be maintained even during logging operations when streamside vegetation is left intact (VDOF 2011, p. 37). The exception for incidental take associated with these activities seeks to ensure these characteristics are maintained for the conservation of the Atlantic pigtoe.

Therefore, under this 4(d) rule, most prohibitions and provisions of 50 CFR 17.21 for endangered wildlife apply to the Atlantic pigtoe, except that incidental take resulting from the following actions is not prohibited:

(1) Species restoration efforts by State wildlife agencies, including collection of broodstock, tissue collection for genetic analysis, captive propagation, and subsequent stocking into currently occupied and unoccupied areas within the historical range of the species, and follow-up monitoring.

(2) Channel restoration projects that create natural, physically stable, ecologically functioning streams (or stream and wetland systems) that are reconnected with their groundwater aquifers. These projects can be accomplished using a variety of methods, but the desired outcome is a natural channel with low shear stress (force of water moving against the channel); bank heights that enable reconnection to the floodplain; a reconnection of surface and groundwater systems, resulting in perennial flows in the channel; riffles and pools composed of existing soil, rock, and wood instead of large imported materials; low compaction of soils within adjacent riparian areas; and inclusion of riparian wetlands. Streams reconstructed in this way would offer suitable habitats for the Atlantic pigtoe and contain stable channel features, such as pools, glides, runs, and riffles, which could be used by the species for spawning, rearing, growth, feeding, dispersal, and other normal behaviors. Prior to restoration action, surveys to determine presence of Atlantic pigtoe must be performed, and if located, mussels must be relocated prior to project implementation.

(3) Bank stabilization projects that use bioengineering methods to replace pre-existing, bare, eroding stream banks with vegetated, stable stream banks, thereby reducing bank erosion and instream sedimentation and improving habitat conditions for the species. Following these bioengineering methods, stream banks may be stabilized using native species live stakes (live, vegetative cuttings inserted or tamped into the ground in a manner that allows the stake to take root and grow), native species live fascines (live branch cuttings, usually willows, bound together into long, cigar-shaped bundles), or native species brush layering (cuttings or branches of easily rooted tree species layered between successive lifts of soil fill). Native species vegetation includes woody and herbaceous species appropriate for the region and habitat conditions. These methods do not include the sole use of quarried rock (rip-rap) or the use of rock baskets or gabion structures.

(4) Forestry-related activities, including silvicultural practices, forest management work, and fire control tactics, that implement State-approved BMPs. In order for this exception to apply to forestry-related activities, these BMPs must achieve all of the following:

(a) Establish a streamside management zone alongside the margins of each waterway.

(b) Restrain visible sedimentation caused by the forestry-related activity from entering the waterway.

(c) Maintain native groundcover within the streamside management zone of the waterway, and promptly re-establish native groundcover if disturbed.

(d) Limit installation of vehicle or equipment crossings of the waterway to only where necessary for the forestry-related activity. Such crossings must:

(i) Have erosion and sedimentation control measures installed to divert surface runoff away and restrain visible sediment from entering the waterway;

(ii) Allow for movement of aquatic organisms within the waterway; and

(iii) Have native groundcover applied and maintained through completion of the forestry-related activity.

(e) Prohibit the use of tracked or wheeled vehicles for reforestation site preparation within the streamside management zone of the waterway.

(f) Prohibit locating log decks, skid trails, new roads, and portable mill sites in the streamside management zone of the waterway.

(g) Prohibit obstruction and impediment of the flow of water within the waterway that is caused by direct deposition of debris or soil by the forestry-related activity.

(h) Maintain shade over the waterway similar to that observed prior to the forestry-related activity.

(i) Prohibit discharge of any solid waste, petroleum, pesticide, fertilizer, or other chemical into the waterway.

We reiterate that these actions and activities may result in some minimal level of take of the Atlantic pigtoe, but they are unlikely to negatively impact the species' conservation and recovery efforts. To the contrary, we expect they would have a net beneficial effect on the

species. Across the species' range, instream habitats have been degraded physically by sedimentation and by direct channel disturbance. The activities in the 4(d) rule will correct some of these problems, creating more favorable habitat conditions for the species.

We may issue permits to carry out otherwise prohibited activities, including those described above, involving threatened wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.32. With regard to threatened wildlife, a permit may be issued for the following purposes: for scientific purposes, to enhance propagation or survival, for economic hardship, for zoological exhibition, for educational purposes, for incidental taking, or for special purposes consistent with the purposes of the Act. The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

We recognize the special and unique relationship with our State natural resource agency partners in contributing to conservation of listed species. State agencies often possess scientific data and valuable expertise on the status and distribution of endangered, threatened, candidate, and at-risk species of wildlife and plants. State agencies, because of their authorities and their close working relationships with local governments and landowners, are in a unique position to assist the Service in implementing all aspects of the Act. In this regard, section 6 of the Act provides that the Service shall cooperate to the maximum extent practicable with the States in carrying out programs authorized by the Act. Therefore, any qualified employee or agent of a State conservation agency that is a party to a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by his or her agency for such purposes, will be able to conduct activities designed to conserve the Atlantic pigtoe that may result in otherwise prohibited take without additional authorization.

Nothing in this 4(d) rule will change in any way the recovery planning provisions of section 4(f) of the Act, the consultation requirements under section 7 of the Act, or the ability of the Service to enter into partnerships for the management and protection of the Atlantic pigtoe. However, interagency cooperation may be further streamlined through planned programmatic consultations for the species between Federal agencies and the Service.

III. Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the Federal agency would be required to consult with the Service under section 7(a)(2) of the Act. However, even if the Service were to conclude that the proposed activity would result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement ''reasonable and prudent alternatives'' to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features within an area, we focus on the specific features that support the life-history needs of the species, including but not limited to, water characteristics, soil type, geological features, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic, or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. We determine whether unoccupied areas are essential for the conservation of the species by considering the life-history, status, and conservation needs of the species. This determination is further informed by any generalized conservation strategy, criteria, or outline that may have been

developed for the species to provide a substantive foundation for identifying which features and specific areas are essential to the conservation of the species and, as a result, the development of the critical habitat designation. For example, an area currently occupied by the species but that was not occupied at the time of listing may be essential to the conservation of the species and may be included in the critical habitat designation.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information from the SSA report and other information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act; (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and (3) the prohibitions found in section 9 of the Act. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of the species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of those planning efforts calls for a different outcome.

On August 27, 2019, we published a final rule in the **Federal Register** (84 FR 45020) to amend our regulations concerning the procedures and criteria used for listing or removing species from the Lists of Endangered and Threatened Wildlife and Plants and designating critical habitat. That rule became effective on September 26, 2019, but, as stated in that rule, the revisions it sets forth apply to classification and critical habitat rules for which a proposed rule was published after September 26, 2019. We published our proposed critical habitat designation for the Atlantic pigtoe on October 11, 2018 (83 FR 51570); therefore, the revisions set forth in the August 27, 2019, final rule do not apply to this final designation of critical habitat for the Atlantic pigtoe and this final rule follows the version of § 424.12 that was in effect prior to September 26, 2019.

Physical or Biological Features Essential to the Conservation of the Species

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas we will designate as critical habitat from within the geographical area occupied by the species at the time of listing, we consider the physical or biological features that are essential to the conservation of the species and which may require special management considerations or protection. The regulations at 50 CFR 424.02 define ''physical or biological features essential to the conservation of the species'' as the features that occur in specific areas and that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity. For example, physical features essential to the conservation of the species might include gravel of a particular size required for spawning, alkaline soil for seed germination, protective cover for migration, or susceptibility to flooding or fire that maintains necessary early-successional habitat characteristics. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting, symbiotic fungi, or a particular level of nonnative species consistent with conservation needs of the listed species. The features may also be combinations of habitat characteristics and may encompass the relationship between characteristics or the necessary amount of a characteristic essential to support the life history of the species.

In considering whether features are essential to the conservation of the species, we may consider an appropriate quality, quantity, and spatial and temporal arrangement of habitat characteristics in the context of the life-history needs, condition, and status of the species. These characteristics include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing (or development) of offspring; and habitats that are protected from disturbance.

Summary of Essential Physical or Biological Features

We derive the specific physical or biological features essential for the conservation of the Atlantic pigtoe from studies of this species' habitat, ecology, and life history. The primary habitat elements that influence resiliency of the Atlantic pigtoe include water quality, water quantity, substrate, and habitat connectivity. A full description of the needs of individuals, populations, and the species is available from the SSA report (Service 2021, p. 11). We have determined that the following physical

or biological features are essential to the conservation of Atlantic pigtoe:

(1) Suitable substrates and connected instream habitats, characterized by geomorphically stable stream channels and banks (*i.e.,* channels that maintain lateral dimensions, longitudinal profiles, and sinuosity patterns over time without an aggrading or degrading bed elevation) with habitats that support a diversity of freshwater mussel and native fish (such as stable riffle-run-pool habitats that provide flow refuges consisting of silt-free gravel and coarse sand substrates).

(2) Adequate flows, or a hydrologic flow regime (which includes the severity, frequency, duration, and seasonality of discharge over time), necessary to maintain benthic habitats where the species is found and to maintain connectivity of streams with the floodplain, allowing the exchange of nutrients and sediment for maintenance of the mussel's and fish hosts' habitat, food availability, spawning habitat for native fishes, and the ability for newly transformed juveniles to settle and become established in their habitats.

(3) Water and sediment quality (including, but not limited to, conductivity, hardness, turbidity, temperature, pH, ammonia, heavy metals, and chemical constituents) necessary to sustain natural physiological processes for normal behavior, growth, and viability of all life stages.

(4) The presence and abundance of fish hosts necessary for recruitment of the Atlantic pigtoe.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection. Special management considerations or protection may be required of the Federal action agency to eliminate, or to reduce to negligible levels, the threats affecting the physical and biological features of each unit. The features essential to the conservation of the Atlantic pigtoe may require special management considerations or protections to reduce the following threats: (1) Urbanization of the landscape, including (but not limited to) land conversion for urban and commercial use, infrastructure (roads, bridges, utilities), and urban water uses (water supply reservoirs, wastewater treatment, etc.); (2) nutrient pollution from agricultural activities that impact water quantity and quality; (3) significant alteration of water quality; (4) incompatible forest management or silviculture activities that remove large areas of forested wetlands or riparian systems; (5) culvert and pipe installation that creates barriers to movement; (6) impacts from invasive species; (7) changes and shifts in seasonal precipitation patterns as a result of climate change; and (8) other watershed and floodplain disturbances that release sediments or nutrients into the water.

Management activities that could ameliorate these threats include, but are not limited to: Use of BMPs designed to reduce sedimentation, erosion, and bank side destruction; protection of riparian corridors and maintenance of sufficient canopy cover along banks; moderation of surface and ground water withdrawals to maintain natural flow regimes; increased use of stormwater management and reduction of stormwater flows into the systems; and reduction of other watershed and floodplain disturbances that release sediments, pollutants, or nutrients into the water.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available information pertaining to the habitat requirements of the species and identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species to be considered for designation as critical habitat.

The current distribution of the Atlantic pigtoe is much reduced from its historical distribution. We anticipate that recovery will require continued protection of existing populations and habitat, and it will need to ensure that there are adequate numbers of mussels occurring in stable populations and that these populations occur over a wide geographic area. This strategy will help to ensure that catastrophic events, such as the effects of hurricanes (*e.g.,* flooding that causes excessive sedimentation, nutrients, and debris to disrupt stream ecology), cannot simultaneously affect all known populations. Rangewide recovery considerations, such as maintaining existing genetic diversity and striving for representation of all major portions of the species' current range, were considered in formulating this critical habitat designation.

Sources of data for the critical habitat designation include multiple databases maintained by universities and State agencies for Virginia and North Carolina, and numerous survey reports on streams throughout the species' range (see SSA report). We have also reviewed available information that pertains to the habitat requirements of this species. Sources of information on habitat requirements include studies conducted at occupied sites and published in peer-reviewed articles, agency reports, and data collected during monitoring efforts (Service 2021, p. 11).

Areas Occupied at the Time of Listing

We identified stream channels that currently support populations of the Atlantic pigtoe. We defined ''current'' as stream channels with observations of the species from 2005 to the present, as described in the SSA report and supported by the species' life history and habitat stability over time (Service 2021, p. 10). Due to the breadth and intensity of survey effort done for freshwater mussels throughout the known range of the species, species experts found that it is reasonable to assume that streams with no positive surveys since 2005 should not be considered occupied for the purpose of our analysis. However, since each particular area is not surveyed every year, and these cryptic mussels have a 42 percent detection probability, only one negative survey would not be sufficient to determine that the species is not present. Therefore, it is reasonable to assume that if the species had been seen within the past 15 years that it could be considered currently occupied. Specific habitat areas were delineated based on Natural Heritage Element Occurrences (EOs) following NatureServe's occurrence delineation protocol for freshwater mussels (NatureServe 2018). These EOs provide habitat for Atlantic pigtoe subpopulations and are large enough to be self-sustaining over time, despite fluctuations in local conditions. The EOs contain stream reaches with interconnected waters so that host fish containing Atlantic pigtoe glochidia can move between areas, at least during certain flows or seasons.

We consider the following streams to be occupied by the species at the time of listing: Craig Creek, Mill Creek, Sappony Creek, Nottoway River Subbasin, Meherrin River, Dan River, Aarons Creek, Little Grassy Creek, Upper/Middle Tar River Subbasin, Sandy/Swift Creek, Fishing Creek

Subbasin, Lower Tar River, Upper Neuse River Subbasin, Middle Neuse River Subbasin, New Hope Creek, Deep River Subbasin, and Little River Subbasin (see Final Critical Habitat Designation, below). The critical habitat designation does not include all streams known to have been occupied by the species historically; instead, it includes only the currently occupied streams within the historical range that have also retained the physical or biological features that will allow for the maintenance and expansion of existing populations.

Areas Outside the Geographic Area Occupied at the Time of Listing

We are not designating any areas outside the geographical area currently occupied by the species because we did not find any unoccupied areas that were essential for the conservation of the species. The protection of eight moderately or highly resilient MUs across the physiographic representation of the range will sufficiently reduce the risk of extinction. Improving the resiliency of populations in the currently occupied streams will increase viability to the point that the protections of the Act are no longer necessary.

Critical Habitat Maps

When determining critical habitat boundaries, we used Geographic Information System (GIS) hydrology data layers that can differ slightly based on the scale of the map; therefore, users should use published coordinates for upstream and downstream boundaries (see **ADDRESSES**). We also made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical or biological features necessary for the Atlantic pigtoe. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this rule have been excluded by text in the rule and are not designated as critical habitat. Therefore, a Federal action involving these lands will not trigger section 7 consultation under the Act with respect to critical habitat and the requirement of no adverse modification unless the specific action will affect the physical or biological features in the adjacent critical habitat.

We are designating as critical habitat areas that we have determined are occupied at the time of listing (*i.e.,* currently occupied) and that contain one or more of the physical or biological features that are essential to support life-history processes of the species. Units are designated based on one or more of the physical or biological features being present to support the Atlantic pigtoe's life-history processes. All units contain all of the identified physical or biological features and support multiple life-history processes.

The critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document under Regulation Promulgation. We include more detailed information on the boundaries of the critical habitat designation in the discussion of individual units below. We will make the coordinates on which each map is based available to the public on *http://www.regulations.gov* under Docket No. FWS–R4–ES–2018–0046.

Final Critical Habitat Designation

We are designating 17 units as critical habitat for the Atlantic pigtoe. The critical habitat areas described below constitute our best assessment at this time of areas that meet the definition of critical habitat. Those 17 units are: (1) Craig Creek, (2) Mill Creek, (3) Sappony Creek, (4) Nottoway River Subbasin, (5) Meherrin River, (6) Dan River, (7) Aarons Creek, (8) Little Grassy Creek, (9) Upper/Middle Tar River Subbasin, (10) Sandy/Swift Creek, (11) Fishing Creek Subbasin, (12) Lower Tar River, (13) Upper Neuse River Subbasin, (14) Middle Neuse River Subbasin, (15) New Hope Creek, (16) Deep River Subbasin, and (17) Little River. Table 2 below shows the occupied units.

TABLE 2—CRITICAL HABITAT UNITS FOR THE ATLANTIC PIGTOE

Critical habitat unit	Riparian ownership	River miles (kilometers)
1. JR1—Craig Creek	Private; Federal	29 (46.7)
2. JR2—Mill Creek	Private	1 (1.6)
3. CR1—Sappony Creek	Private	4 (6.6)
4. CR2—Nottoway River Subbasin	Private; Federal	64 (103)
5. CR3—Meherrin River	Private	5 (8)
6. RR1—Dan River	Private	14 (22.5)
7. RR2—Aarons Creek	Private	12 (19.3)
8. RR3—Little Grassy Creek	Private	3 (4.8)
9. TR1—Upper/Middle Tar River Subbasin	Private; Easements	91 (146.5)
10. TR2—Sandy/Swift Creek	Private; State; Easements	50 (80.5)
11. TR3—Fishing Creek Subbasin	Private; State; Easements	85 (136.8)
12. TR4—Lower Tar River	Private; State; Easements	30 (48.3)
13. NR1—Upper Neuse River Subbasin	Private; State; Easements	60 (95)
14. NR2—Middle Neuse River Subbasin	Private; State; County; Easements	61 (98.2)
15. CF1—New Hope Creek	Private; Easements	4 (6.4)
16. CF2—Deep River Subbasin	Private	10 (16.1)
17. YR1– Little River	Private; Easements	40 (64.4)
Total		563 (906)

Note: Mileage may not sum due to rounding.

We present brief descriptions of all units, and reasons why they meet the definition of critical habitat for the Atlantic pigtoe, below. All units are considered occupied.

James River Population

Unit 1: JR1—Craig Creek, Craig and Botetourt Counties, Virginia

Unit 1 consists of 29 river mi (46.7 river km) of Craig Creek near VA Route 616 northeast of New Castle downstream to just below VA Route 817 crossing. The land adjacent to Craig Creek is primarily private, although approximately 1 mi (1.6 km) of land along the river is federally owned by George Washington and Jefferson National Forest (GWJ NF), and 2.5 mi (4 km) consists of conservation easements. The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

Special management considerations or protection may be required to address excess nutrients, sediment, and pollutants that enter the creek and serve as indicators of other forms of pollution such as bacteria and toxins, reducing water quality for the species. Sources of these types of pollution are wastewater, agricultural runoff, and urban stormwater runoff. Five stream reaches, totaling approximately 21 river miles, are impaired for aquatic life in the lower Craig Creek watershed. Impairment is indicated by low benthic-macroinvertebrate bioassessments, pH issues, high temperature, and fecal coliform. Given the stormwater and nonpoint source pollution identified as contributing to water quality issues in this unit, special management considerations including riparian buffer restoration, reduced surface and groundwater withdrawals, stormwater retrofits, eliminating direct stormwater discharges, and implementing highest levels of wastewater treatment practicable will benefit the species' habitat in this unit.

The GWJ NF surrounds the Craig Creek Subbasin; protections and management of the GWJ NF will likely enable habitat conditions (water quality, water quantity/flow, instream substrate, and connectivity) to remain high into the future. Targeted species restoration in conjunction with current associated-species restoration efforts in Johns, Dicks, and Little Oregon Creeks within the Craig Creek Subbasin will likely improve the Atlantic pigtoe's resiliency in these areas. Maintenance of forested buffer conditions is essential to retaining high-quality instream habitat in this unit.

Unit 2: JR2—Mill Creek, Bath County, Virginia

Unit 2 consists of a 1-mile (1.6-km) segment of Mill Creek at the VA39 (Mountain Valley Road) crossing. The land surrounding the creek is privately owned. The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

Special management considerations or protection may be required within Unit 2 to address excess nutrients, sediment, and pollutants that enter the creek and serve as indicators of other forms of pollution such as bacteria and toxins. Sources of these types of pollution are wastewater, agricultural runoff, and urban stormwater runoff. Given the urban stormwater and nonpoint source pollution identified as contributing to water quality issues in this unit, special management considerations including riparian buffer restoration, reduced surface and groundwater withdrawals, stormwater retrofits, eliminating direct stormwater discharges, increasing open space in the watershed, and implementing highest levels of wastewater treatment practicable will benefit the species' habitat in this unit.

The GWJ NF surrounds most of the Mill Creek watershed; protections and management of the GWJ NF will likely enable habitat conditions to remain high into the future. Targeted species restoration in conjunction with current associated-species restoration efforts in Mill Creek will likely improve the Atlantic pigtoe's resiliency in these areas. Maintenance of forested buffer conditions is essential to retaining high-quality instream habitat in this unit.

Chowan River Population

Unit 3: CR1—Sappony Creek, Dinwiddie County, Virginia

Unit 3 consists of 4 river miles (6.6 river km) of Sappony Creek beginning just upstream of the Seaboard Railroad crossing and ending just downstream of the Shippings Road (SR709) crossing. The riparian areas on either side of the river are privately owned. The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

Special management considerations or protection may be required to address excess sediment and pollutants that enter the creek and serve as indicators of other forms of pollution such as bacteria and toxins, reducing water quality for the species. Sources of these types of pollution are likely agricultural and silvicultural runoff. Special management focused on agricultural and silviculture BMPs, maintenance of forested buffers, and connection of protected riparian corridors will benefit habitat for the species in this unit.

Unit 4: CR2—Nottoway River Subbasin, Nottoway, Lunenburg, Brunswick, Dinwiddie, Greensville, and Sussex Counties, Virginia

Unit 4 consists of 64 river miles (103 river km) of the Nottoway River, and a portion of Sturgeon Creek, beginning downstream of the Nottoway River's confluence with Dickerson Creek and ending just downstream of Little Mill Road, and includes Sturgeon Creek upstream of Old Stage Road. Land bordering the river is primarily privately owned, although some of the land is part of the Fort Pickett National Guard Installation (see Exemptions, below), containing 14.2 mi (23 km) of conservation parcels. The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

Special management considerations or protection may be required within this unit to address a variety of threats. In the past decade, the Nottoway River suffered from several seasonal drought events, which not only caused very low dissolved oxygen conditions but also decreased food delivery because of minimal flows. In addition, these conditions led to increased predation rates on potential host fishes that were concentrated into low-flow refugia (*e.g.,* pools). Urban stormwater and nonpoint source pollution have been identified as contributing to water quality issues in this unit; therefore, special management considerations for riparian buffer restoration, reduced surface and groundwater withdrawals, and stormwater retrofits will benefit the habitat in this unit. Additional special management considerations or protection may be required within this unit to address low water levels as a result of water withdrawals and drought.

Unit 5: CR3—Meherrin River, Brunswick County, Virginia

Unit 5 consists of 5 river miles (8 river km) of the Meherrin River, from approximately 1.5 miles below the confluence with Saddletree Creek under VA Highway 46 (Christana Highway) to VA715 (Iron Bridge Road). The land on either side of the river is privately owned. The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

Special management considerations or protection may be required within

this unit to address a variety of threats. Like the Nottoway River, the Meherrin River has been affected by seasonal droughts, resulting in low flow conditions and low dissolved oxygen conditions. The rural nature of the unit will benefit from following agricultural and silvicultural BMPs. Additional special management considerations or protection such as riparian buffer protection, reduced surface and groundwater withdrawals, and water conservation programs may be required within this unit to address low water levels as a result of water withdrawals and drought.

Roanoke River Population

Unit 6: RR1—Dan River, Pittsylvania County, Virginia, and Rockingham County, North Carolina

Unit 6 consists of 14 river miles (22.5 river km) of the Dan River along the border of Virginia and North Carolina from just upstream of NC Highway 700 near Eden, North Carolina, into Pittsylvania County, Virginia, and downstream to the confluence with Williamson Creek in Rockingham County, North Carolina. The land on either side of the river is privately owned. The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

Special management considerations or protection may be required within this unit to address threats. For example, a Duke Energy Coal Ash spill occurred upstream of this unit in February 2014; subsequent actions related to mitigating the effects of the spill will ultimately benefit the habitat in this unit, potentially allowing species restoration efforts.

Unit 7: RR2—Aarons Creek, Granville County, North Carolina, and Mecklenburg and Halifax Counties, Virginia

Unit 7 consists of 12 river miles (19.3 river km) of Aarons Creek, from NC96 in Granville County, North Carolina, downstream across the North Carolina-Virginia border to just upstream of VA602 (White House Road) along the Mecklenburg County-Halifax County line in Virginia. Land on either side of the river is privately owned. The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

Special management considerations or protection may be required within this unit to address a variety of threats. There are two impaired stream reaches totaling approximately 12 river miles (19.3 river km) in the Aarons Creek watershed. An ''impairment'' designation by the State here is a result of low dissolved oxygen and low benthic-macroinvertebrate assessment scores. Special management focused on maintaining riparian buffers and following BMPs will be important for the habitat in this unit.

Unit 8: RR3—Little Grassy Creek, Granville County, North Carolina

Unit 8 consists of 3 river miles (4.8 river km) of Little Grassy Creek in Granville County, North Carolina, beginning at the Crawford Currin Road crossing and ending at the confluence with Grassy Creek. The riparian areas on either side of the river are privately owned. The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

Special management considerations or protection may be required to address excess sediment and pollutants that enter the creek and serve as indicators of other forms of pollution such as bacteria and toxins, reducing water quality for the species. Sources of these types of pollution are likely agricultural and silvicultural runoff. Given the nonpoint source pollution identified as contributing to water quality issues in this unit, special management considerations related to riparian buffer protection and restoration and reduced surface and groundwater withdrawals will benefit the species' habitat in this unit.

Tar River Population

Unit 9: TR1—Upper/Middle Tar River Subbasin, Granville, Vance, Franklin, and Nash Counties, North Carolina

This unit consists of 91 river miles (146.5 river km) of the mainstem of the upper and middle Tar River as well as several tributaries (Bear Swamp Creek, Fox Creek, Crooked Creek, Cub Creek, and Shelton Creek), all in North Carolina. The portion of Cub Creek starts near Hobgood Road and continues to the confluence with the Tar River; the Tar River portion starts just upstream of the NC158 bridge and goes downstream to the NC 581 crossing; the Shelton Creek portion starts upstream of NC158 and goes downstream to the confluence with the Tar River; the Bear Swamp Creek portion begins upstream of Dyking Road and goes downstream to the confluence with the Tar River (and includes an unnamed tributary upstream of Beasley Road); the Fox Creek portion begins downstream of NC 561 and goes to the confluence with the Tar River; and the Crooked Creek portion begins upstream of NC98 crossing and goes downstream to confluence with Tar River. Land bordering the river and creeks is mostly privately owned (79 mi (119 km)), with some areas in public ownership or easements (12 mi (17 km)). The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

Special management considerations or protection may be required within this unit to address a variety of threats. Excessive amounts of nitrogen and phosphorus run off the land or are discharged into the waters, causing too much growth of microscopic or macroscopic vegetation and leading to extremely low levels of dissolved oxygen. As a result, there are six ''impaired'' stream reaches (as defined on the State's 303d list) totaling approximately 32 river miles in the unit. Expansion or addition of new wastewater discharges are also a threat to habitat in this unit. Special management focused on agricultural BMPs, implementing highest levels of treatment of wastewater practicable, maintenance of forested buffers, and connection of protected riparian corridors will benefit habitat for the species in this unit.

Unit 10: TR2—Sandy/Swift Creek, Warren, Franklin, and Nash Counties, North Carolina

This unit consists of a 50-mile (80.5-km) segment of Sandy/Swift Creek beginning at Southerland Mill Road and continuing downstream to NC301. Land bordering the river and creeks is mostly privately owned (42 mi (80 km)), with some areas covered by protective easements (8 mi (13 km)). The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

Special management considerations or protection may be required within this unit to address a variety of threats. Excessive amounts of nitrogen and phosphorus run off the land or are discharged into the waters, causing excessive growth of microscopic or macroscopic vegetation and leading to extremely low levels of dissolved oxygen; there is one ''impaired'' stream reach totaling approximately 5 river miles (8 river km) in this unit. Given the nonpoint source pollution identified as contributing to water quality issues in this unit, special management considerations including riparian buffer protection and restoration, connection of protected riparian corridors, reduced surface and groundwater withdrawals,

and stormwater retrofits will benefit habitat for the species in this unit.

Unit 11: TR3—Fishing Creek Subbasin, Warren, Halifax, Franklin, and Nash Counties, North Carolina

This unit consists of 85 river miles (136.8 river km) in Fishing Creek, Little Fishing Creek, Shocco Creek, and Maple Branch. The Shocco Creek portion begins downstream of the NC58 bridge and continues to the confluence with Fishing Creek; the entirety of Maple Branch is included, down to the confluence with Fishing Creek; Fishing Creek begins at Axtell Ridgeway Road (SR1112) downstream to I–95; and Little Fishing Creek begins upstream of Briston Brown Road (SR1532) downstream to the confluence with Fishing Creek. The land bordering the creeks includes private parcels (56 miles (90 km)), protective easements (14 miles (23 km)), and State game lands (15 miles (24 km)). The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

Special management considerations or protection may be required within this unit to address a variety of threats. Excessive amounts of nitrogen and phosphorus run off the land or are discharged into the waters, causing excessive growth of microscopic or macroscopic vegetation and leading to extremely low levels of dissolved oxygen. Given the nonpoint source pollution identified as contributing to water quality issues in this unit, special management considerations including riparian buffer restoration, reduced surface and groundwater withdrawals, and stormwater retrofits will benefit habitat for the species in this unit.

Unit 12: TR4—Lower Tar River, Edgecombe and Pitt Counties, North Carolina

This unit consists of 30 river miles (48.3 river km) of the Lower Tar River, lower Swift Creek, and Fishing Creek in Edgecombe County, North Carolina, from NC97 near Leggett, North Carolina, to the Edgecombe-Pitt County line near NC33. Land along the river is divided between private parcels, protective easements, State game lands, and State park land. The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

Special management considerations or protection may be required within this unit to address a variety of threats. Excessive amounts of nitrogen and phosphorus run off the land or are discharged into the waters, causing excessive growth of microscopic or macroscopic vegetation and leading to extremely low levels of dissolved oxygen. Special management focused on agricultural BMPs, maintenance of forested buffers, and connection of protected riparian corridors will benefit habitat for the species in this unit.

Neuse River Population

Unit 13: NR1—Upper Neuse River Subbasin, Person, Durham, and Orange Counties, North Carolina

This unit consists of 60 river miles (95 river km) in four reaches including Flat River, Little River, Eno River, and the Upper Eno River. The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

The Flat River reach consists of 19 river miles (30.6 river km) in the Flat River Subbasin in Person and Durham Counties, North Carolina, including the South Flat River downstream of Dick Coleman Road, the North Flat River near Parsonage Road, and Deep Creek near Helena-Moriah Road downstream where each river converges into the Flat River downstream of State Forest Road. Land along the Flat River subunit includes mostly private parcels, with some easements (1 mi (1.7 km)) and State forest land (1.4 mi (2.3 km)).

The Little River Subbasin includes 18 river miles (29 river km) of the North Fork and South Fork Little Rivers in Orange and Durham Counties, North Carolina, bordered by mostly private land and 0.2 mi (0.4 km) of conservation easements.

The Upper Eno River reach consists of 4 river miles (6.4 river km) in Orange County, North Carolina, including the West Fork Eno River upstream of Cedar Grove Road to the confluence with McGowan Creek. This subunit is bordered by 3 miles (4.8 km) of private land and 1 mile (1.6 km) of conservation parcels.

The Eno River reach consists of 18 river miles (29 river km) in Orange and Durham Counties, North Carolina, from below Eno Mountain Road to NC15–501. Land bordering the river contains nearly all State park land (17 mi (27.4 km)) and 0.3 mi (0.45 km) of conservation parcels; the remaining land is privately owned.

Special management considerations or protection may be required within this unit to address a variety of threats. Large quantities of nutrients (especially nitrogen) contributed by fertilizers and animal waste washed from lawns, urban developed areas, farm fields, and animal operations are impacting aquatic ecosystems in this unit. More than 300 permitted point-source sites discharge wastewater into streams and rivers in the basin. Development is also impacting areas along the Upper Neuse River. Special management considerations in this unit include using the highest available wastewater treatment technologies, retrofitting stormwater systems, eliminating direct stormwater discharges, increasing open space, maintaining connected riparian corridors, and treating invasive species (like hydrilla).

Unit 14: NR2—Middle Neuse River Subbasin, Wake, Johnston, Wilson Counties, North Carolina

This unit consists of 61 river miles (98.2 river km) in five reaches including Swift Creek, Middle Creek, Upper Little River, Middle Little River, and Contentnea Creek, all in North Carolina. The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe and currently supports some breeding, feeding, and sheltering needs for the species.

The Middle Creek reach is 19 river miles (30.6 river km) below Old Stage Road downstream to below Crantock Road, and the Swift Creek reach is 25 river miles (40.2 river km) from Lake Benson downstream to confluence with the Neuse, both in Wake and Johnston Counties. They are primarily bordered by private land with 1.2 mi (1.9 km) of easement parcels.

The Upper Little River reach includes 4 river miles (6.4 river km) of the Upper Little River from the confluence with Perry Creek to Fowler Road in Wake County, North Carolina. The land along this stream reach is primarily county-owned (3.4 mi (5.4 km) with some private parcels.

The Middle Little River reach includes 11 river miles (17.7 river km) from Atkinsons Mill downstream to NC301 in Johnston County, North Carolina. This area is bordered predominantly by private land and 0.2 mi (0.4 km) of conservation parcels.

The Contentnea Creek reach consists of 2 river miles (3.2 river km) below Buckhorn Reservoir to just below Sadie Road near NC581 in Wilson County, North Carolina, bordered entirely by private land.

Special management considerations or protection may be required within this unit to address a variety of threats. Large quantities of nutrients (especially nitrogen) contributed by fertilizers and animal waste washed from lawns, urban developed areas, farm fields, and animal operations are impacting aquatic ecosystems in this unit. More than 300 permitted point-source sites discharge wastewater into streams and rivers in

the basin. Development is also impacting areas along the Middle Neuse River.

There are 49 State-defined ''impaired'' stream reaches totaling approximately 447 river miles (719.4 river km) in this unit. There are many factors that cause an impairment label to be given by the State, including low benthic-macroinvertebrate assessment scores, low pH, poor fish community scores, low dissolved oxygen, polychlorinated biphenyls (PCBs), copper, and zinc. There are 349 non-major and 6 major (Apex Water Reclamation Facility, Central Johnston County Waste Water Treatment Plant, Cary Waste Water Treatment Plant, City of Raleigh Wastewater Treatment Plant, Dempsey Benton Water Treatment Plant, and Terrible Creek Waste Water Treatment Plant) permitted discharges in this MU. Special management related to developed areas, including using the best available wastewater treatment technologies, retrofitting stormwater systems, eliminating direct stormwater discharges, increasing open space in the watershed, and maintaining connected riparian corridors, will be important to maintain habitat in this unit.

Cape Fear Population

Unit 15: CF1—New Hope Creek, Orange County, North Carolina

This unit consists of 4 river miles (6.4 river km) of habitat in the New Hope Creek from NC86 to Mimosa Road. The land bordering the creek includes private parcels and 2.5 mi (4 km) of conservation easements. The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

Special management considerations or protection may be required within this unit to address a variety of threats. Large quantities of nutrients (especially nitrogen) contributed by fertilizers and animal waste washed from lawns, urban developed areas, farm fields, and animal operations are impacting aquatic ecosystems in this unit. More than 200 permitted point-source sites discharge wastewater into streams and rivers in the basin. Development is also impacting areas along New Hope Creek.

Special management, including using the best available wastewater treatment technologies, retrofitting stormwater systems, eliminating direct stormwater discharges, increasing open space in the watershed, and maintaining connected riparian corridors, may be required to maintain habitat in this unit.

Unit 16: CF2—Deep River Subbasin, Randolph County, North Carolina

The Deep River Subbasin unit consists of 10 river miles (16.1 river km), including the mainstem between Richland and Brush Creeks as well as Richland Creek from Little Beane Store Road to the confluence with the Deep River and Brush Creek from Brush Creek Road to the confluence with the Deep River. Land bordering the area is privately owned. The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

The Deep River Subbasin is situated in a mostly rural part of the Cape Fear River Basin, and large-scale agriculture and livestock operations are present. Special management considerations or protection may be required within this unit to ensure the use of agriculture BMPs, especially preventing cattle access to streams, as well as protecting forested riparian buffers to benefit habitat in this unit. The invasive plant hydrilla has recently been identified in the Deep River, and special management will likely be required to eradicate the infestation to improve habitat conditions to meet the breeding, feeding, and sheltering needs of Atlantic pigtoe.

Yadkin-Pee Dee River Population

Unit 17: YR1—Little River, Randolph and Montgomery Counties, North Carolina

This unit consists of 40 river miles (64.4 river km) of Little River from SR1114 downstream to Okeewemee Star Road, including the West Fork Little River from NC134 to the confluence with the Little River. Land along the river is predominantly privately owned, with 0.7 mi (1.15 km) of parcels in conservation easements. The unit contains all of the physical or biological features that are essential to support life-history processes of the Atlantic pigtoe.

Habitat fragmentation from dams and reservoirs is impacting the aquatic ecosystems in this unit. Sedimentation from intensive agriculture is the top pollution problem in the basin. Special management considerations or protection may include the use of agricultural BMPs, especially preventing cattle access to streams, as well as protecting forested riparian buffers to benefit habitat in this unit.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species.

We published a final rule revising the definition of destruction or adverse modification on August 27, 2019 (84 FR 44976). Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, Tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat—and actions on State, Tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal agency—do not require section 7 consultation.

Compliance with the requirements of section 7(a)(2) is documented through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Service Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 set forth requirements for Federal agencies to reinitiate formal consultation on previously reviewed actions. These requirements apply when the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law) and, subsequent to the previous consultation: (1) If the amount or extent of taking specified in the incidental take statement is exceeded; (2) if new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered; (3) if the identified action is subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the biological opinion; or (4) if a new species is listed or critical habitat designated that may be affected by the identified action.

In such situations, Federal agencies sometimes may need to request reinitiation of consultation with us, but the regulations also specify some exceptions to the requirement to reinitiate consultation on specific land management plans after subsequently listing a new species or designating new critical habitat. See the regulations for a description of those exceptions.

Application of the ''Adverse Modification'' Standard

The key factor related to the adverse modification determination is whether implementation of the proposed Federal action directly or indirectly alters the designated critical habitat in a way that appreciably diminishes the value of the critical habitat as a whole for the conservation of the listed species. As discussed above, the role of critical habitat is to support physical or biological features essential to the conservation of a listed species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may violate section 7(a)(2) of the Act by destroying or adversely modifying such habitat, or that may be affected by such designation.

Activities that the Service may, during a consultation under section 7(a)(2) of the Act, consider likely to destroy or adversely modify critical habitat include, but are not limited to:

(1) Actions that would alter the minimum flow or the existing flow regime. Such activities could include, but are not limited to, impoundment, channelization, water diversion, water withdrawal, and hydropower generation. These activities could eliminate or reduce the habitat necessary for the growth and reproduction of the Atlantic pigtoe by decreasing or altering flows to levels that would adversely affect its ability to complete its life cycle.

(2) Actions that would significantly alter water chemistry or temperature. Such activities could include, but are not limited to, release of chemicals (including pharmaceuticals, metals, and salts), biological pollutants, or heated effluents into the surface water or connected groundwater at a point source or by dispersed release (non-point source). These activities could alter water conditions to levels that are beyond the tolerances of the Atlantic pigtoe and result in direct or cumulative adverse effects to individuals and their life cycles.

(3) Actions that would significantly increase sediment deposition within the stream channel. Such activities could include, but are not limited to, excessive sedimentation from livestock grazing, road construction, channel alteration, incompatible forestry activities, off-road vehicle use, and other watershed and floodplain disturbances. These activities could eliminate or reduce the habitat necessary for the growth and reproduction of the Atlantic pigtoe by increasing the sediment deposition to levels that would adversely affect its ability to complete its life cycle.

(4) Actions that would significantly increase the filamentous algal community within the stream channel. Such activities could include, but are not limited to, release of nutrients into the surface water or connected groundwater at a point source or by dispersed release (non-point source). These activities can result in excessive filamentous algae filling streams and reducing habitat for the Atlantic pigtoe, degrading water quality during algal decay, and decreasing oxygen levels at night from algal respiration to levels below the tolerances of the mussel.

(5) Actions that would significantly alter channel morphology or geometry. Such activities could include, but are not limited to, channelization, impoundment, road and bridge construction, mining, dredging, and destruction of riparian vegetation. These activities may lead to changes in water flows and levels that would degrade or eliminate the Atlantic pigtoe and/or its habitats. These actions can also lead to increased sedimentation and degradation in water quality to levels that are beyond the tolerances of the Atlantic pigtoe.

(6) Actions that result in the introduction, spread, or augmentation of nonnative aquatic species in occupied stream segments, or in stream segments that are hydrologically connected to occupied stream segments, even if those segments are occasionally intermittent, or introduction of other species that compete with or prey on the Atlantic pigtoe. Possible actions could include, but are not limited to, stocking of nonnative fishes or other related actions. These activities can introduce parasites or disease to mollusks; result in direct predation; or affect the growth, reproduction, and survival of Atlantic pigtoes.

Finally, we note that for any of the six categories of actions outlined above, we and the relevant Federal agency may find that the agency's anticipated actions affecting critical habitat may be appropriate to consider programmatically in section 7 consultation. Programmatic consultations can be an efficient method for streamlining the consultation process by addressing an agency's multiple similar, frequently occurring, or routine actions expected to be implemented in a given geographic area. Programmatic section 7 consultation can also be conducted for an agency's proposed program, plan, policy, or regulation that provides a framework for future proposed actions. We are committed to responding to any agency's request for a programmatic consultation, when appropriate and subject to the approval of the Service Director, as a means to streamline the regulatory process and avoid time-consuming and inefficient multiple individual consultations.

Exemptions

Application of Section 4(a)(3) of the Act

The Sikes Act Improvement Act of 1997 (Sikes Act) (16 U.S.C. 670a) required each military installation that includes land and water suitable for the conservation and management of natural resources to complete an integrated natural resources management plan (INRMP) by November 17, 2001. An INRMP integrates implementation of the military mission of the installation with stewardship of the natural resources found on the base. Each INRMP includes:

(1) An assessment of the ecological needs on the installation, including the need to provide for the conservation of listed species;

(2) A statement of goals and priorities;

(3) A detailed description of management actions to be implemented to provide for these ecological needs; and

(4) A monitoring and adaptive management plan.

Among other things, each INRMP must, to the extent appropriate and applicable, provide for fish and wildlife management; fish and wildlife habitat enhancement or modification; wetland protection, enhancement, and restoration where necessary to support fish and wildlife; and enforcement of applicable natural resource laws.

The National Defense Authorization Act for Fiscal Year 2004 (Pub. L. 108–136) amended the Act to limit areas eligible for designation as critical habitat. Specifically, section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that the Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an INRMP prepared under 16 U.S.C. 670a, if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.

We consult with the military on the development and implementation of INRMPs for installations with listed species. We analyze INRMPs developed by military installations located within the range of critical habitat designations to determine if they meet the criteria for exemption from critical habitat under section 4(a)(3) of the Act.

Approved INRMPs

We have identified one area within the critical habitat designation that consists of Department of Defense lands with a completed, Service-approved INRMP. The Army National Guard—Maneuver Training Center Fort Pickett (Fort Pickett) is located in southeastern Virginia on 41,000 acres in three counties: Nottoway, Brunswick, and Dinwiddie. Fort Pickett is federally owned land that is managed by the Virginia Army National Guard and is subject to all federal laws and regulations. The Fort Pickett INRMP covers fiscal years 2017–2021, and serves as the principal management plan governing all natural resource activities on the installation. Among the goals and objectives listed in the INRMP is habitat management for rare, threatened, and endangered species, and the Atlantic pigtoe is included in this plan. Management actions that benefit the Atlantic pigtoe include maintenance and improvement of habitat, monitoring mussel populations, and improving water quality. Additional elements of the management actions included in the INRMP that will benefit Atlantic pigtoe and its habitat are forest management, stream and wetland protection zones, and public outreach and education.

Fourteen river miles (22.5 km) of Unit 4 (CR2—Nottoway River Subbasin) are located within the area covered by this INRMP. Based on the above considerations, and in accordance with section 4(a)(3)(B)(i) of the Act, we have determined that the identified streams are subject to the Fort Pickett INRMP and that conservation efforts identified in the INRMP will provide a benefit to the Atlantic pigtoe. Therefore, streams within this installation are exempt from critical habitat designation under section 4(a)(3) of the Act. We are not including approximately 14 river miles (22.5 river km) of habitat in this critical habitat designation because of this exemption.

Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if we determine that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless we determine, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making the determination to exclude a particular area, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor. On December 18, 2020, we published a final rule in the **Federal Register** (85 FR 82376) revising portions of our regulations pertaining to exclusions of critical habitat. These final regulations became effective on January 19, 2021, and apply to critical habitat rules for which a proposed rule was published after January 19, 2021. Consequently, these new regulations do not apply to this final rule.

Under section 4(b)(2) of the Act, we may exclude an area from designated critical habitat based on economic impacts, impacts on national security, or any other relevant impacts. In considering whether to exclude a particular area from the designation, we identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and evaluate whether the benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the Secretary may exercise discretion to exclude the area only if such exclusion would not result in the extinction of the species. We describe below the process that we undertook for taking into consideration each category of impacts and our analyses of the relevant impacts.

Consideration of Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. In order to consider economic impacts, we prepared an incremental effects memorandum (IEM) and screening analysis which, together with our narrative and interpretation of effects we consider our draft economic analysis (DEA) of the proposed critical habitat designation and related factors (IEc, 2018, entire). The analysis, dated April 13, 2018, was made available for public review from October 11, 2018, through December 10, 2018 (83 FR 51570). We then accepted public comments on the analysis for an additional 30 days, from September 22, 2020, through October 22, 2020, when we published a revised proposed critical habitat designation (85 FR 59487). The DEA addressed probable economic impacts of critical habitat designation for the Atlantic pigtoe. Following the close of the comment periods, we reviewed and evaluated all information submitted during the comment periods that may pertain to our consideration of the probable incremental economic

impacts of this critical habitat designation. Additional information relevant to the probable incremental economic impacts of critical habitat designation for the Atlantic pigtoe is summarized below and available in the screening analysis for the Atlantic pigtoe (IEc, 2018, entire), available at *http://www.regulations.gov.*

Executive Orders (E.O.s) 12866 and 13563 direct Federal agencies to assess the costs and benefits of available regulatory alternatives in quantitative (to the extent feasible) and qualitative terms. Consistent with the E.O. regulatory analysis requirements, our effects analysis under the Act may take into consideration impacts to both directly and indirectly affected entities, where practicable and reasonable. If sufficient data are available, we assess to the extent practicable the probable impacts to both directly and indirectly affected entities. As part of our screening analysis, we considered the types of economic activities that are likely to occur within the areas likely affected by the critical habitat designation. In our March 19, 2018, IEM describing probable incremental economic impacts that may result from the proposed designation, we first identified probable incremental economic impacts associated with each of the following categories of activities: (1) Federal lands management (National Park Service, U.S. Forest Service, Department of Defense); (2) agriculture; (3) forest management/silviculture/timber; (4) development; (5) recreation; (6) restoration activities; and (7) transportation. We considered each industry or category individually. Additionally, we considered whether the activities have any Federal involvement. Critical habitat designation generally will not affect activities that do not have any Federal involvement; under the Act, designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies. This rule lists the Atlantic pigtoe as a threatened species, and, on the effective date of this rule (see **DATES**, above), in areas where the Atlantic pigtoe is present, under section 7 of the Act, Federal agencies will be required to consult with the Service on activities they fund, permit, or implement that may affect the species.

In our IEM, we attempted to clarify the distinction between the effects that will result from the species being listed and those attributable to the critical habitat designation (*i.e.,* difference between the jeopardy and adverse modification standards) for the Atlantic pigtoe. Because critical habitat is being designated concurrently with the listing, it has been our experience that it is more difficult to discern which conservation efforts are attributable to the species being listed and those which will result solely from the designation of critical habitat. However, the following specific circumstances in this case help to inform our evaluation: (1) The essential physical or biological features identified for critical habitat are the same features essential for the life requisites of the species, and (2) any actions that would result in sufficient harm or harassment to constitute jeopardy to the Atlantic pigtoe would also likely adversely affect the essential physical or biological features of critical habitat. The IEM outlines our rationale concerning this limited distinction between baseline conservation efforts and incremental impacts of the designation of critical habitat for this species. This evaluation of the incremental effects has been used as the basis to evaluate the probable incremental economic impacts of this designation of critical habitat.

The critical habitat designation for the Atlantic pigtoe totals approximately 563 river miles (906 river km), all of which are currently occupied by the species. In these areas, any actions that may affect the species or its habitat will likely also affect critical habitat, and it is unlikely that any additional conservation efforts will be required to address the adverse modification standard over and above those recommended as necessary to avoid jeopardizing the continued existence of the species. Therefore, the only additional costs that are expected in all of the critical habitat designations are administrative costs, due to the fact that this additional analysis will require time and resources by both the Federal action agency and the Service. However, it is believed that, in most circumstances, these costs would not reach the threshold of ''significant'' under E.O. 12866. We anticipate a maximum of 109 section 7 consultations annually at a total incremental cost of less than $230,000 per year. The addition of two units did not affect the economic analysis because the analysis was done at county level, and the new units were included in the initial calculations.

Exclusions

Exclusions Based on Economic Impacts

As discussed above, the Service considered the economic impacts of this critical habitat designation, and the Secretary is not exercising her discretion to exclude any areas from this designation of critical habitat for the Atlantic pigtoe based on economic impacts. A copy of the IEM and screening analysis with supporting documents may be obtained by contacting the Raleigh Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**) or by downloading from the internet at *http://www.regulations.gov.*

Exclusions Based on National Security Impacts or Homeland Security Impacts

Section 4(a)(3)(B)(i) of the Act (see Exemptions, above) may not cover all Department of Defense lands or areas that pose potential national-security concerns (*e.g.,* a DoD installation that is in the process of revising its INRMP for a newly listed species or a species previously not covered). If a particular area is not covered under section 4(a)(3)(B)(i), national-security or homeland-security concerns are not a factor in the process of determining what areas meet the definition of ''critical habitat.'' Nevertheless, when designating critical habitat under section 4(b)(2), the Service must consider impacts on national security, including homeland security, on lands or areas not covered by section 4(a)(3)(B)(i). Accordingly, we will always consider for exclusion from the designation areas for which Department of Defense, Department of Homeland Security, or another Federal agency has requested exclusion based on an assertion of national-security or homeland-security concerns. We have determined that, other than the land exempted under section 4(a)(3)(B)(i) of the Act based upon the existence of an approved INRMP (see Exemptions, above), the lands within the designation of critical habitat for the Atlantic pigtoe are not owned or managed by the Department of Defense or Department of Homeland Security. Furthermore, we did not receive any requests for exclusion from any federal agency responsible for homeland or national security. Therefore, we anticipate no impact on national security, and the Secretary is not exercising her discretion to exclude any areas from the final designation based on impacts on national security.

Exclusions Based on Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security. Other relevant impacts may include, but are not limited to, impacts to Tribes, States, local governments, public health and safety, community interests, the environment (such as increased risk of

wildfire or pest and invasive species management), Federal lands, and conservation plans, agreements, or partnerships. To identify other relevant impacts that may affect the exclusion analysis, we consider a number of factors, including whether there are permitted conservation plans covering the species in the area such as HCPs, safe harbor agreements, or candidate conservation agreements with assurances, or whether there are non-permitted conservation agreements and partnerships that may be impaired by designation of, or exclusion from, critical habitat. In addition, we look at whether Tribal conservation plans and partnerships, Tribal resources, or government-to-government relationships of the United States with Tribal entities may be affected by the designation. We also consider any State, local, public-health, community-interest, environmental, or social impacts that might occur because of the designation.

In preparing this designation, we have determined that there are currently no HCPs or other management plans for the Atlantic pigtoe, and the designation does not include any Tribal lands or trust resources. We anticipate no impact on Tribal lands, partnerships, or HCPs from this critical habitat designation. Accordingly, the Secretary is not exercising her discretion to exclude any areas from the final designation based on other relevant impacts.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine whether potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

Under the RFA, as amended, and as understood in the light of recent court decisions, Federal agencies are required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself; in other words, the RFA does not require agencies to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies will be directly regulated by this critical habitat designation. The RFA does not require evaluation of the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities will be directly regulated by this rulemaking, the Service certifies that this critical habitat designation will not have a significant economic impact on a substantial number of small entities.

In summary, we have considered whether the designation will result in a significant economic impact on a substantial number of small entities. For the above reasons and based on currently available information, we certify that this critical habitat designation will not have a significant economic impact on a substantial number of small business entities. Therefore, a regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. In our economic analysis, we did not find that the designation of this critical habitat will significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(1) This final rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both ''Federal

intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or Tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and Tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or Tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this final rule will significantly or uniquely affect small governments because the government-owned lands being designated as critical habitat are owned by the States of Virginia and North Carolina. These government entities do not fit the definition of ''small governmental jurisdiction.'' Therefore, a Small Government Agency Plan is not required.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for Atlantic pigtoe in a takings implications assessment. The Act does not authorize the Service to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, or establish any closures, or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify critical habitat. A takings implications assessment has been completed and concludes that this designation of critical habitat for Atlantic pigtoe does not pose significant takings implications for lands within or affected by the designation.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this final rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of this critical habitat designation with, appropriate State resource agencies in Virginia and North Carolina. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, the final rule does not have substantial direct effects either on the States, or on the relationship between the national government and the States, or on the distribution of powers and responsibilities among the various levels of government. The designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the physical or biological features of the habitat necessary to the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist these local governments in long-range planning because these local governments no longer have to wait for case-by-case section 7 consultations to occur.

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) will be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We are designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, this final rule identifies the physical or biological features essential to the conservation of the species. The areas of designated critical habitat are presented on maps, and the rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (NEPA), need not be prepared in connection with adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We have identified no Tribal interests that will be affected by this rule.

References Cited

A complete list of all references cited is available on the internet at *http://www.regulations.gov* and upon request from the Raleigh Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this rule are the staff members of the U.S. Fish and Wildlife Service Species Assessment Team and Raleigh Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h) by adding an entry for ''Pigtoe, Atlantic'' to the List of Endangered and Threatened Wildlife in alphabetical order under CLAMS to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
CLAMS				
*	*	*	*	*
Pigtoe, Atlantic	*Fusconaia masoni*	Wherever found	T	86 FR [insert **Federal Register** page where the document begins], November 16, 2021; 50 CFR 17.45(a); [4d] 50 CFR 17.95(f).[CH]
*	*	*	*	*

■ 3. Revise § 17.45 to read as follows:

§ 17.45 Special rules—snails and clams.

(a) Atlantic pigtoe (*Fusconaia masoni*)—(1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to the Atlantic pigtoe. Except as provided under paragraphs (a)(2) and (3) of this section and §§ 17.4 and 17.5, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed, any of the following acts in regard to this species:

(i) Import or export, as set forth at § 17.21(b) for endangered wildlife.

(ii) Take, as set forth at § 17.21(c)(1) for endangered wildlife.

(iii) Possession and other acts with unlawfully taken specimens, as set forth at § 17.21(d)(1) for endangered wildlife.

(iv) Interstate or foreign commerce in the course of commercial activity, as set forth at § 17.21(e) for endangered wildlife.

(v) Sale or offer for sale, as set forth at § 17.21(f) for endangered wildlife.

(2) *General exceptions from prohibitions.* In regard to this species, you may:

(i) Conduct activities as authorized by a permit under § 17.32.

(ii) Take, as set forth at § 17.21(c)(2) through (c)(4) for endangered wildlife.

(iii) Take, as set forth at § 17.31(b).

(iv) Possess and engage in other acts with unlawfully taken Atlantic pigtoe, as set forth at § 17.21(d)(2) through (4) for endangered wildlife.

(3) *Exceptions from prohibitions for specific types of incidental take.* The following entities and activities that cause take that is incidental to an otherwise lawful activity are not in violation of the prohibitions:

(i) Species restoration efforts by State wildlife agencies, including collection of broodstock, tissue collection for genetic analysis, captive propagation, and subsequent stocking into currently occupied and unoccupied areas within the historical range of the species, and follow-up monitoring.

(ii) Channel restoration projects that create natural, physically stable, ecologically functioning streams (or stream and wetland systems) that are reconnected with their groundwater aquifers. These projects can be accomplished using a variety of methods, but the desired outcome is a natural channel with low shear stress (force of water moving against the channel); bank heights that enable reconnection to the floodplain; a reconnection of surface and

groundwater systems, resulting in perennial flows in the channel; riffles and pools comprised of existing soil, rock, and wood instead of large imported materials; low compaction of soils within adjacent riparian areas; and inclusion of riparian wetlands. Streams reconstructed in this way would offer suitable habitats for the Atlantic pigtoe and contain stable channel features, such as pools, glides, runs, and riffles, which could be used by the species and its host fish for spawning, rearing, growth, feeding, migration, and other normal behaviors. Prior to restoration action, surveys to determine presence of Atlantic pigtoe must be performed, and if located, mussels must be relocated prior to project implementation.

(iii) Bank stabilization projects that use bioengineering methods to replace pre-existing, bare, eroding stream banks with vegetated, stable stream banks, thereby reducing bank erosion and instream sedimentation and improving habitat conditions for the species. Following these bioengineering methods, stream banks may be stabilized using native species live stakes (live, vegetative cuttings inserted or tamped into the ground in a manner that allows the stake to take root and grow), native species live fascines (live branch cuttings, usually willows, bound together into long, cigar-shaped bundles), or native species brush layering (cuttings or branches of easily rooted tree species layered between successive lifts of soil fill). Native vegetation includes woody species appropriate for the region and habitat conditions. These methods do not include the sole use of quarried rock (rip-rap) or the use of rock baskets or gabion structures.

(iv) Forestry-related activities, including silvicultural practices, forest management work, and fire control tactics, that implement State-approved best management practices. In order for this exception to apply to forestry-related activities, these best management practices must achieve all of the following:

(A) Establish a streamside management zone alongside the margins of each waterway.

(B) Restrain visible sedimentation caused by the forestry-related activity from entering the waterway.

(C) Maintain native groundcover within the streamside management zone of the waterway, and promptly re-establish native groundcover if disturbed.

(D) Limit installation of vehicle or equipment crossings of the waterway to only where necessary for the forestry-related activity. Such crossings shall:

(*1*) Have erosion and sedimentation control measures installed to divert surface runoff away and restrain visible sediment from entering the waterway;

(*2*) Allow for movement of aquatic organisms within the waterway; and

(*3*) Have native groundcover applied and maintained through completion of the forestry-related activity.

(E) Prohibit the use of tracked or wheeled vehicles for reforestation site preparation within the streamside management zone of the waterway.

(F) Prohibit locating log decks, skid trails, new roads, and portable mill sites in the streamside management zone of the waterway.

(G) Prohibit obstruction and impediment of the flow of water within the waterway that is caused by direct deposition of debris or soil by the forestry-related activity.

(H) Maintain shade over the waterway similar to that observed prior to the forestry-related activity.

(I) Prohibit discharge of any solid waste, petroleum, pesticide, fertilizer, or other chemical into the waterway.

(b) [Reserved]

■ 4. Amend § 17.95(f) immediately following the entry for ''Rabbitsfoot (*Quadrilla cylindrica cylindrica*)'' by adding an entry for ''Atlantic Pigtoe (*Fusconaia masoni*)'' to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(f) *Clams and Snails.*

* * * * *

Atlantic Pigtoe (Fusconaia masoni)

(1) Critical habitat units are depicted for Bath, Botetourt, Brunswick, Craig, Dinwiddie, Greensville, Halifax, Lunenburg, Mecklenburg, Nottoway, Pittsylvania, and Sussex Counties in Virginia, and Durham, Edgecombe, Franklin, Granville, Halifax, Johnston, Montgomery, Nash, Orange, Person, Pitt, Randolph, Rockingham, Vance, Wake, Warren, and Wilson Counties in North Carolina, on the maps in this entry.

(2) Within these areas, the physical or biological features essential to the conservation of Atlantic pigtoe consist of the following components:

(i) Suitable substrates and connected instream habitats, characterized by geomorphically stable stream channels and banks (*i.e.,* channels that maintain lateral dimensions, longitudinal profiles, and sinuosity patterns over time without an aggrading or degrading bed elevation) with habitats that support a diversity of freshwater mussel and native fish (such as stable riffle-run-pool habitats that provide flow refuges consisting of silt-free gravel and coarse sand substrates).

(ii) Adequate flows, or a hydrologic flow regime (which includes the severity, frequency, duration, and seasonality of discharge over time), necessary to maintain benthic habitats where the species is found and to maintain connectivity of streams with the floodplain, allowing the exchange of nutrients and sediment for maintenance of the mussel's and fish hosts' habitat, food availability, spawning habitat for native fishes, and the ability for newly transformed juveniles to settle and become established in their habitats.

(iii) Water and sediment quality (including, but not limited to, conductivity, hardness, turbidity, temperature, pH, ammonia, heavy metals, and chemical constituents) necessary to sustain natural physiological processes for normal behavior, growth, and viability of all life stages.

(iv) The presence and abundance of fish hosts necessary for recruitment of the Atlantic pigtoe.

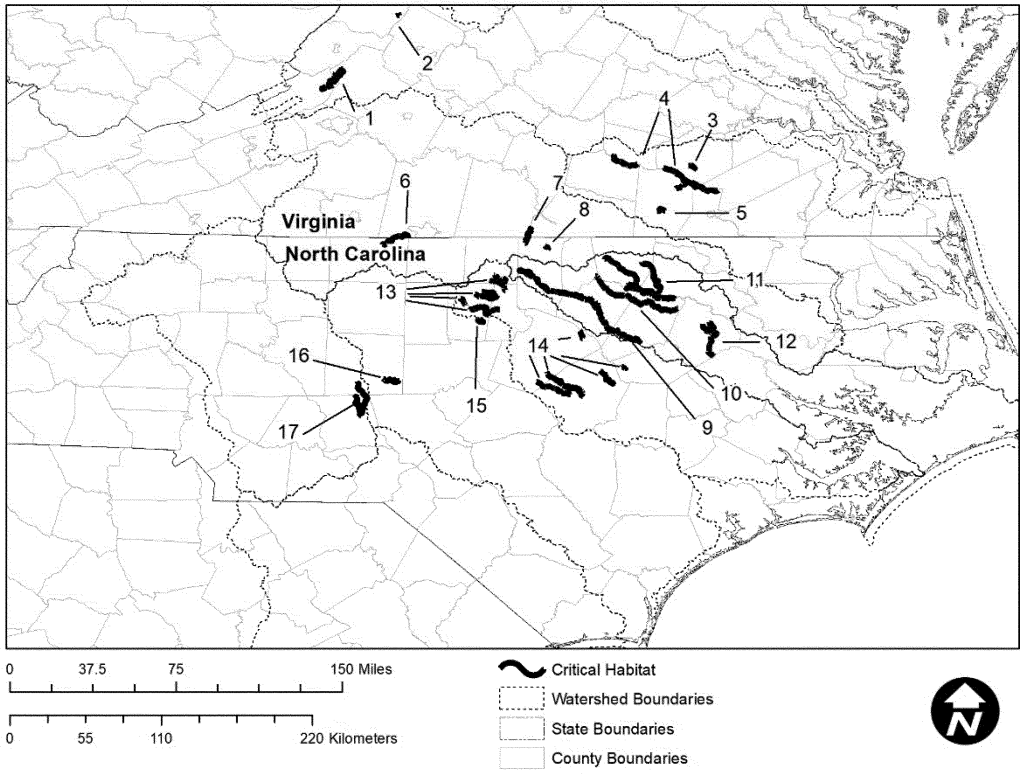
(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on December 16, 2021.

(4) Data layers defining map units were created by overlaying Natural Heritage Element Occurrence data and U.S. Geological Survey (USGS) hydrologic data for stream reaches. The hydrologic data used in the critical habitat maps were extracted from the USGS 1:1M scale nationwide hydrologic layer (*https://nationalmap.gov/small_scale/mld/1nethyd.html)* with a projection of EPSG:4269–North American Datum of 1983 (NAD83) Geographic. The North Carolina and Virginia Natural Heritage program species presence data and the Virginia Department of Wildlife Resources species data were used to select specific stream segments for inclusion in the critical habitat layer. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points on which each map is based are available to the public at *http://www.regulations.gov* under Docket No. FWS–R4–ES–2018–0046 and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) Note: Index map follows:

BILLING CODE 4333–15–P

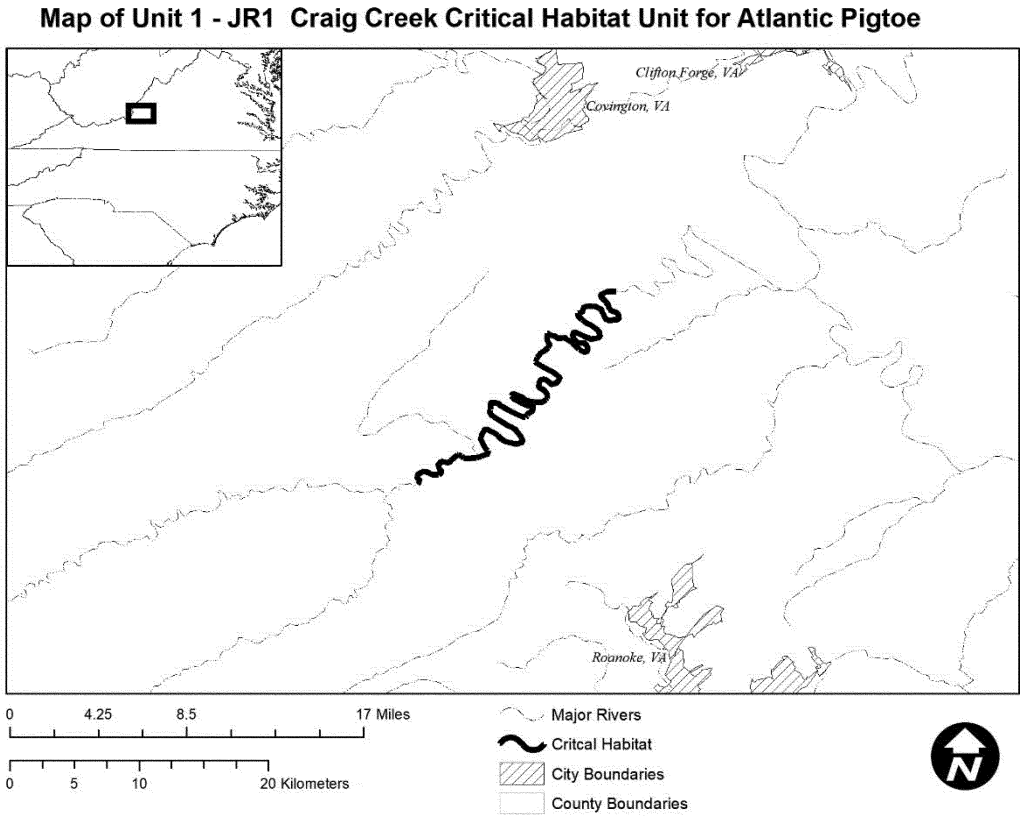
Index Map of Critical Habitat Units for Atlantic Pigtoe



(6) Unit 1: JR1—Craig Creek, Craig and Botetourt Counties, Virginia.

(i) This unit consists of 29 river miles (46.7 river kilometers (km)) of Craig Creek near VA Route 616 northeast of New Castle downstream to just below VA Route 817 crossing.

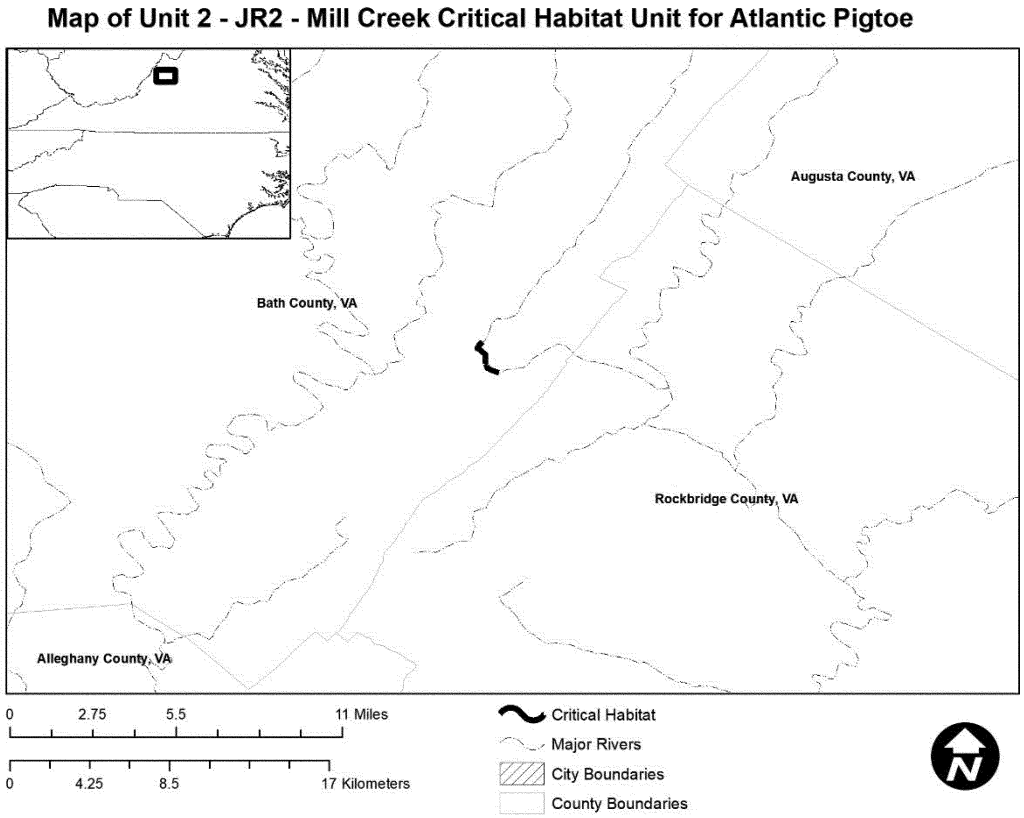
(ii) Map of Unit 1 (Craig Creek) follows:



(7) Unit 2: JR2—Mill Creek, Bath County, Virginia.

(i) This unit consists of a 1-mile (1.6-km) segment of Mill Creek at the VA39 (Mountain Valley Road) crossing.

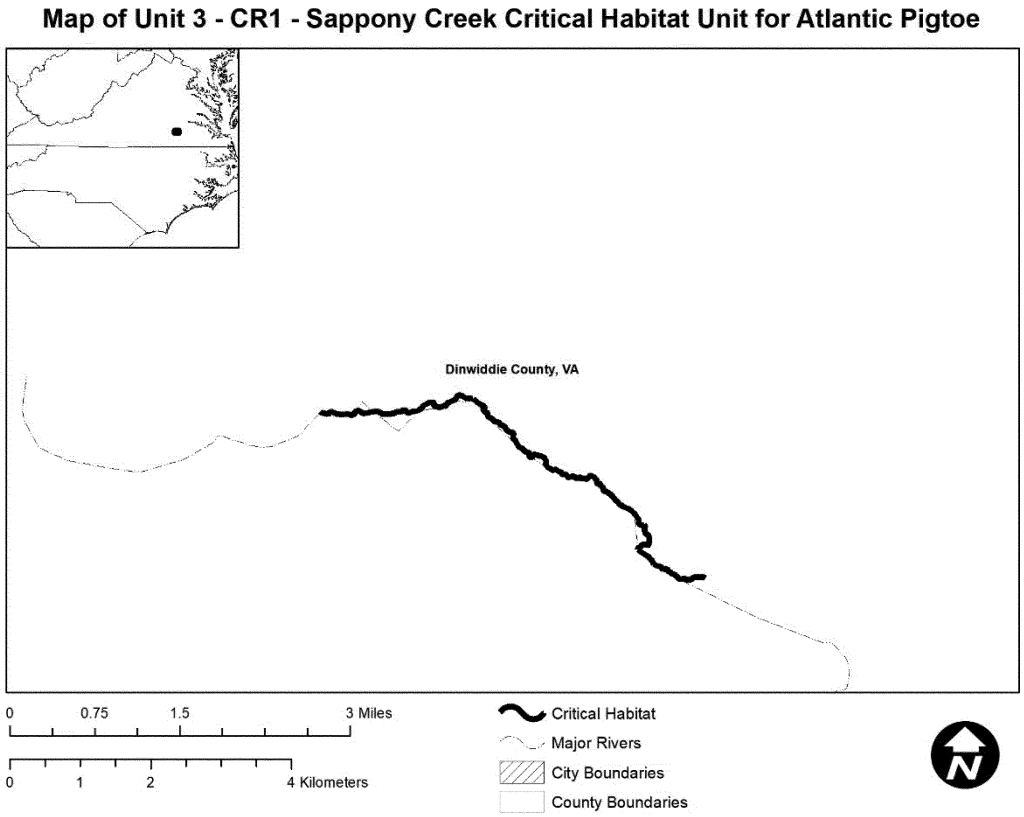
(ii) Map of Unit 2 (Mill Creek) follows:



(8) Unit 3: CR1—Sappony Creek, Dinwiddie County, Virginia.

(i) This unit consists of 4 river miles (6.6 river km) of Sappony Creek beginning just upstream of the Seaboard Railroad crossing and ending just downstream of the Shippings Road (SR709) crossing.

(ii) Map of Unit 3 (Sappony Creek) follows:

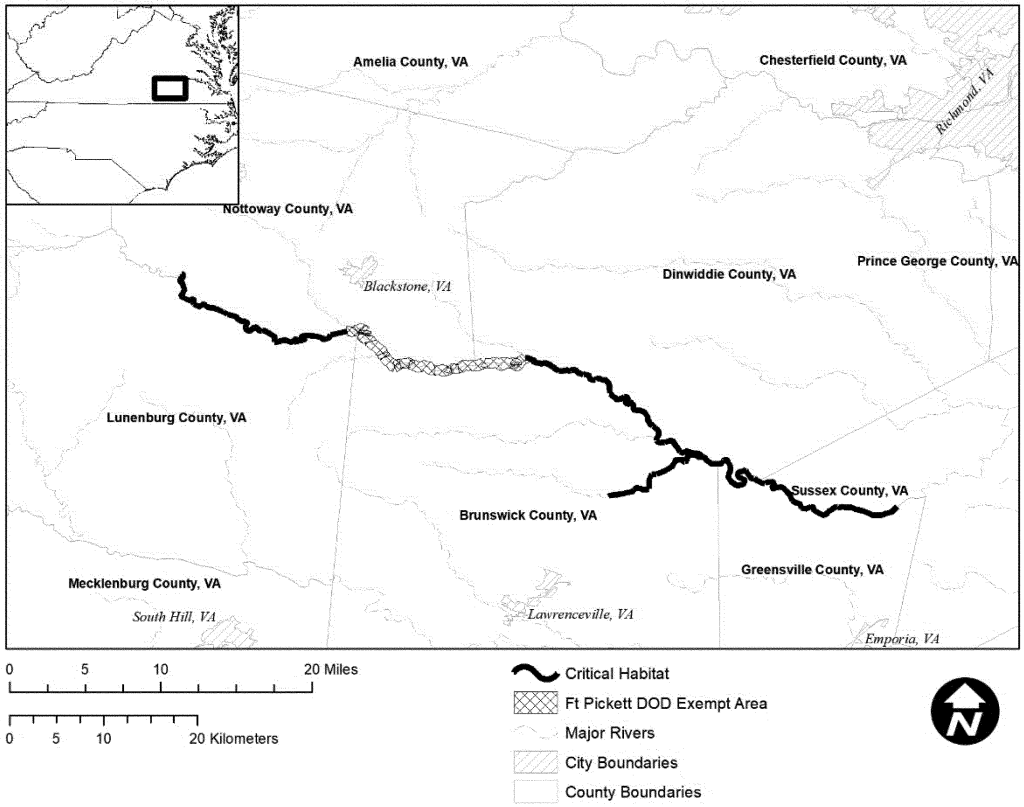


(9) Unit 4: CR2—Nottoway River Subbasin, Nottoway, Lunenburg, Brunswick, Dinwiddie, Greensville, and Sussex Counties, Virginia.

(i) This unit consists of 64 river miles (103 river km) of the Nottoway River, and a portion of Sturgeon Creek, beginning downstream of the Nottoway River's confluence with Dickerson Creek and ending just downstream of Little Mill Road, and includes Sturgeon Creek upstream of Old Stage Road. Land bordering the river is primarily privately owned, although some of the land along the river is part of the Fort Pickett National Guard Installation.

(ii) Map of Unit 4 (Nottoway River Subbasin) follows:

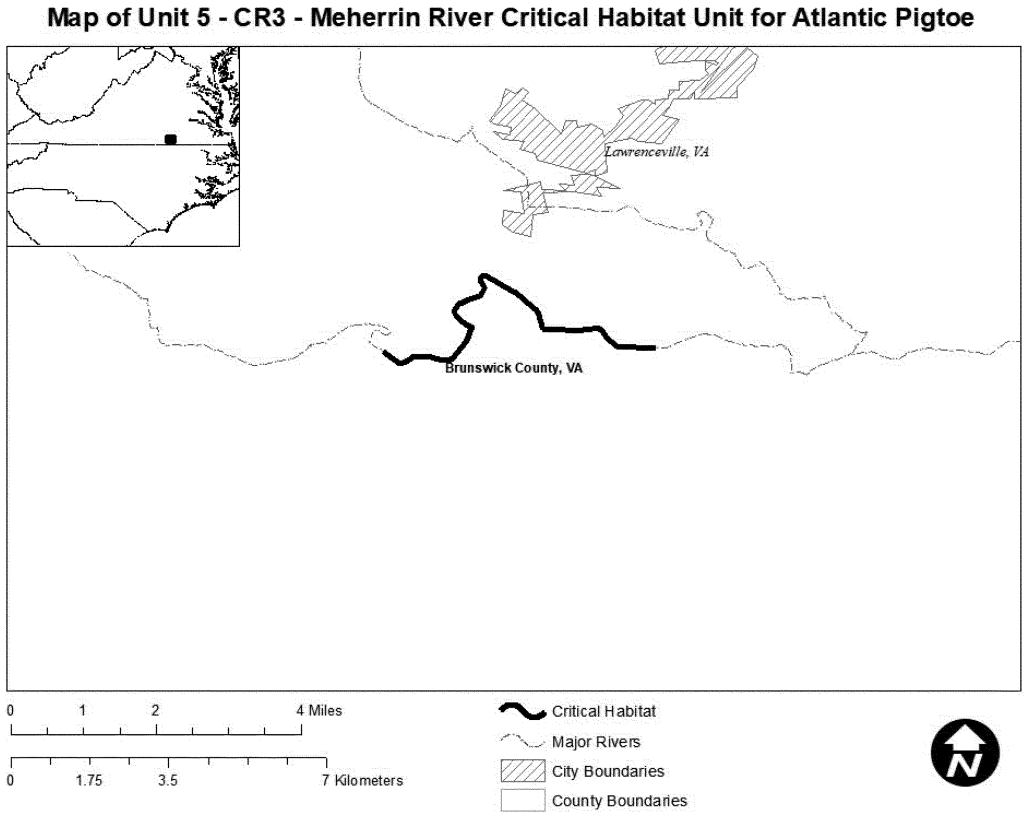
Map of Unit 4 - CR2 - Nottaway River Subbasin Critical Habitat Unit for Atlantic Pigtoe



(10) Unit 5: CR3—Meherrin River, Brunswick County, Virginia.

(i) This unit consists of 5 river miles (8 river km) of the Meherrin River from approximately 1.5 miles below the confluence with Saddletree Creek under VA Highway 46 (Christana Highway) to VA715 (Iron Bridge Road).

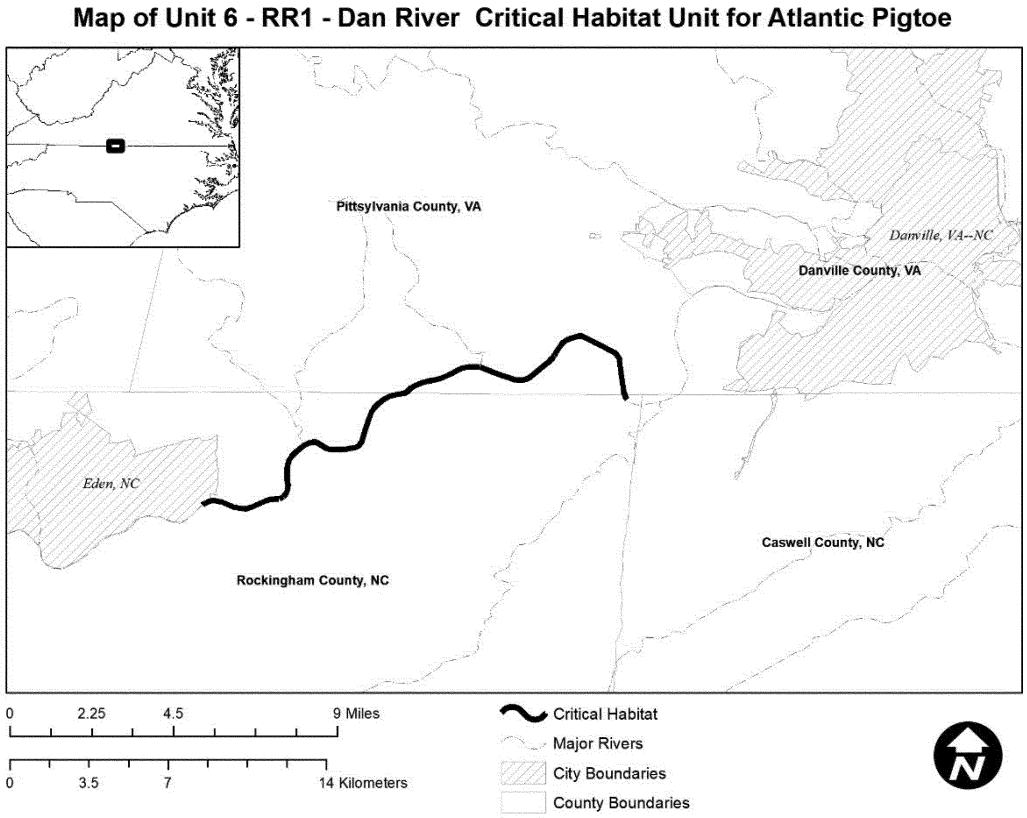
(ii) Map of Unit 5 (Meherrin River) follows:



(11) Unit 6: RR1—Dan River, Pittsylvania County, Virginia, and Rockingham County, North Carolina.

(i) This unit consists of 14 river miles (22.5 river km) of the Dan River along the border of Virginia and North Carolina from just upstream of NC Highway 700 near Eden, North Carolina, into Pittsylvania County, Virginia, and downstream to the confluence with Williamson Creek in Rockingham County, North Carolina.

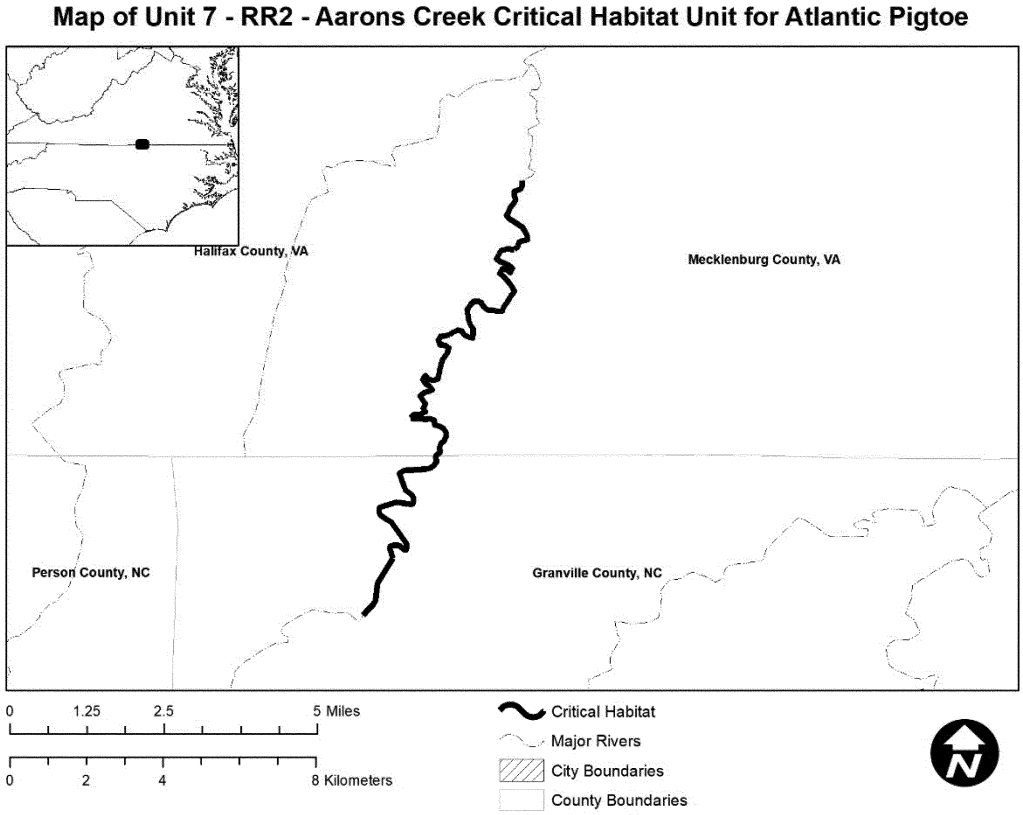
(ii) Map of Unit 6 (Dan River) follows:



(12) Unit 7: RR2—Aarons Creek, Granville County, North Carolina, and Mecklenburg and Halifax Counties, Virginia.

(i) This unit consists of 12 river miles (19.3 river km) of Aarons Creek, from NC96 in Granville County, North Carolina, downstream across the North Carolina-Virginia border to just upstream of VA602 (White House Road) along the Mecklenburg County-Halifax County line in Virginia.

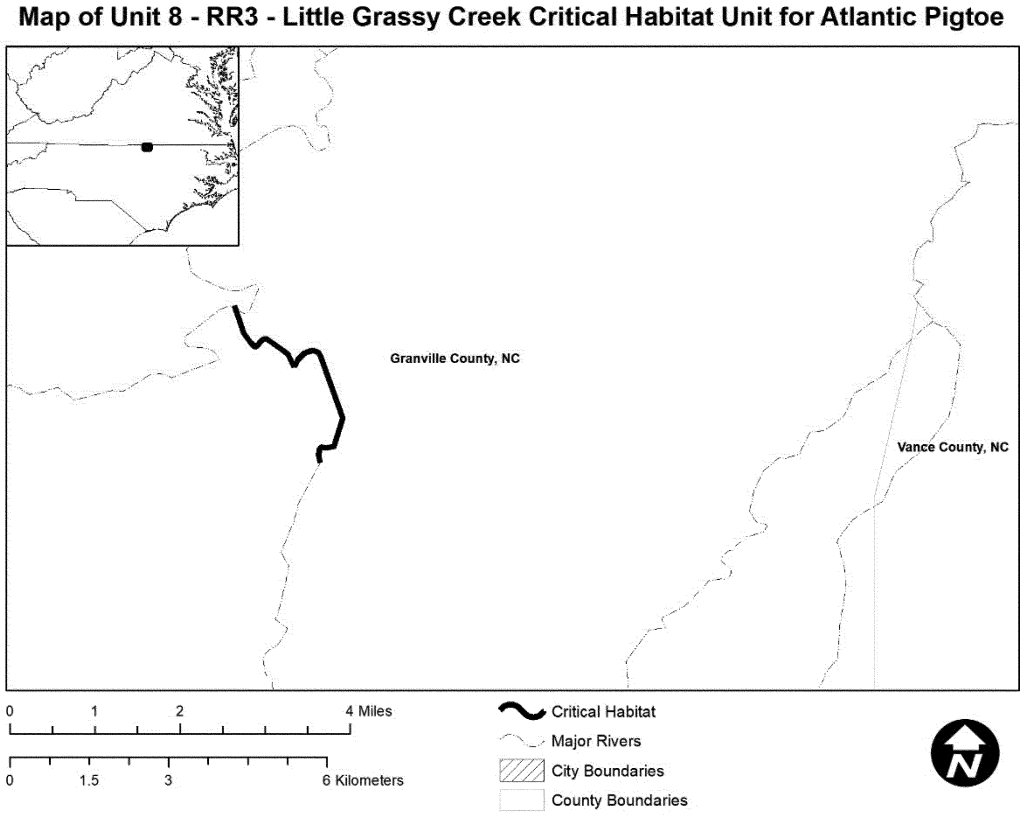
(ii) Map of Unit 7 (Aarons Creek) follows:



(13) Unit 8: RR3—Little Grassy Creek, Granville County, North Carolina.

(i) This unit consists of 3 river miles (4.8 river km) of Little Grassy Creek in Granville County, North Carolina, beginning at the Crawford Currin Road crossing and ending at the confluence with Grassy Creek.

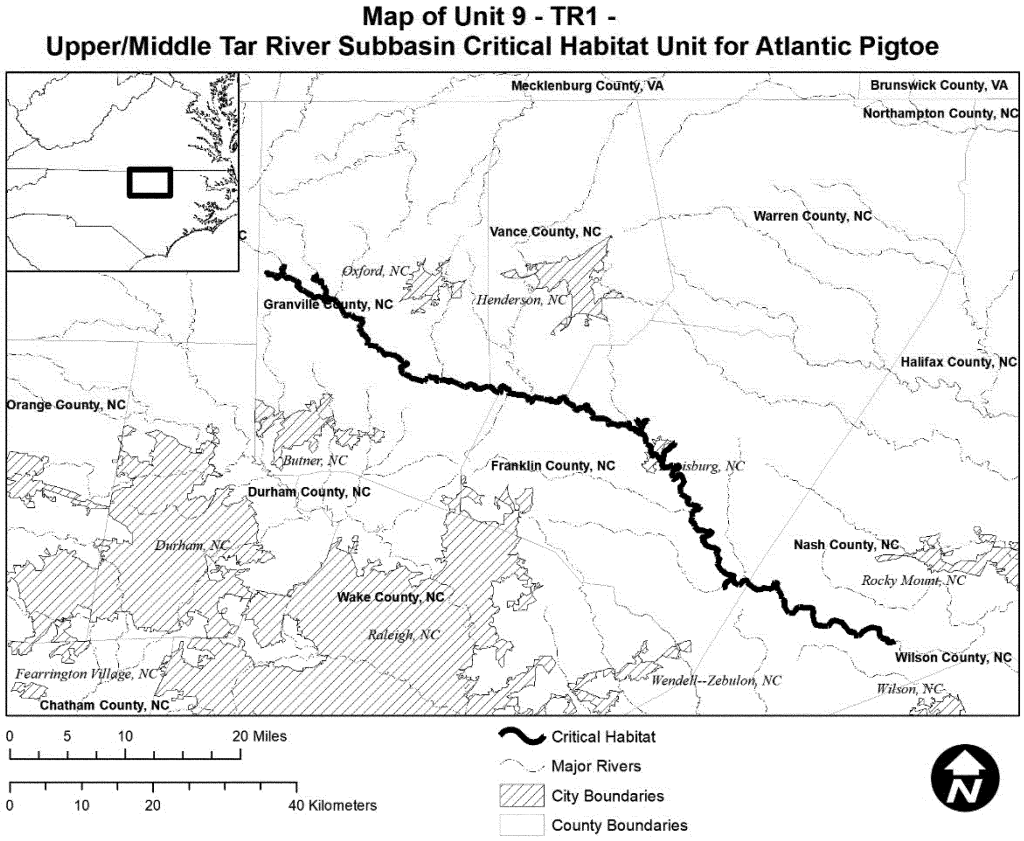
(ii) Map of Unit 8 (Little Grassy Creek) follows:



(14) Unit 9: TR1—Upper/Middle Tar River Subbasin, Granville, Vance, Franklin, and Nash Counties, North Carolina.

(i) This unit consists of 91 river miles (146.5 river km) of the mainstem of the upper and middle Tar River as well as several tributaries (Bear Swamp Creek, Fox Creek, Crooked Creek, Cub Creek, and Shelton Creek), all in North Carolina. The portion of Cub Creek starts near Hobgood Road and continues to the confluence with the Tar River; the Tar River portion starts just upstream of the NC158 bridge and goes downstream to the NC581 crossing; the Shelton Creek portion starts upstream of NC158 and goes downstream to the confluence with the Tar River; the Bear Swamp Creek portion begins upstream of Dyking Road and goes downstream to the confluence with the Tar River (and includes an unnamed tributary upstream of Beasley Road); the Fox Creek portion begins downstream of NC561 and goes to the confluence with the Tar River; and the Crooked Creek portion begins upstream of NC98 crossing and goes downstream to confluence with Tar River.

(ii) Map of Unit 9 (Upper/Middle Tar River Subbasin) follows:

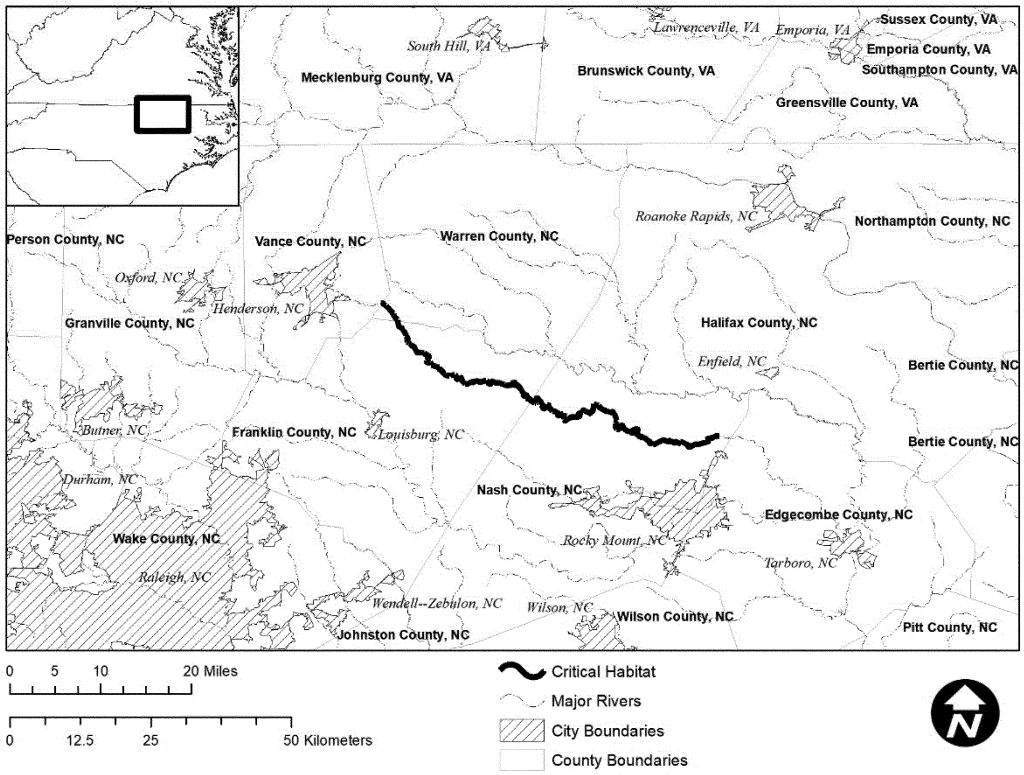


(15) Unit 10: TR2—Sandy/Swift Creek, Warren, Franklin, and Nash Counties, North Carolina.

(i) This unit consists of a 50-mile (80.5-km) segment of Sandy/Swift Creek beginning at Southerland Mill Road and continuing downstream to NC301.

(ii) Map of Unit 10 (Sandy/Swift Creek) follows:

Map of Unit 10 - TR2 - Sandy/Swift Creek Critical Habitat Unit for Atlantic Pigtoe

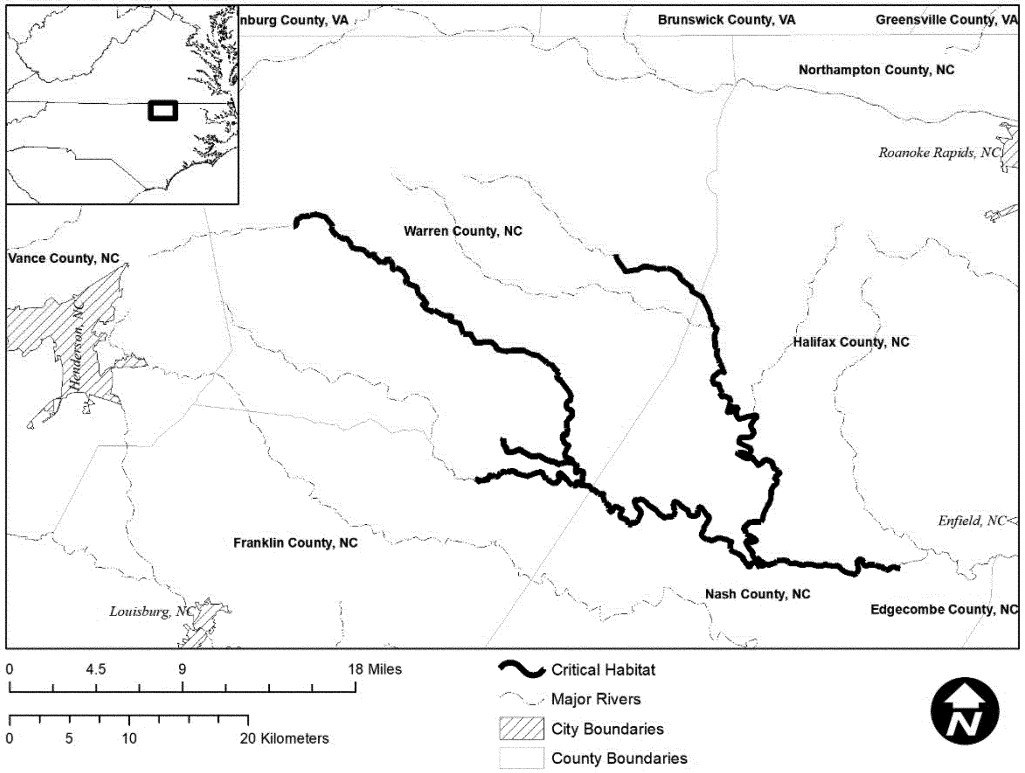


(16) Unit 11: TR3—Fishing Creek Subbasin, Warren, Halifax, Franklin, and Nash Counties, North Carolina.

(i) This unit consists of 85 river miles (136.8 river km) in Fishing Creek, Little Fishing Creek, Shocco Creek, and Maple Branch. The Shocco Creek portion begins downstream of the NC58 bridge and continues to the confluence with Fishing Creek; the entirety of Maple Branch is included, down to the confluence with Fishing Creek; Fishing Creek begins at Axtell Ridgeway Road (SR1112) and goes downstream to I–95; and Little Fishing Creek begins upstream of Briston Brown Road (SR1532) and goes downstream to the confluence with Fishing Creek.

(ii) Map of Unit 11 (Fishing Creek Subbasin) follows:

Map of Unit 11 - TR3 - Fishing Creek Subbasin Critical Habitat Unit for Atlantic Pigtoe

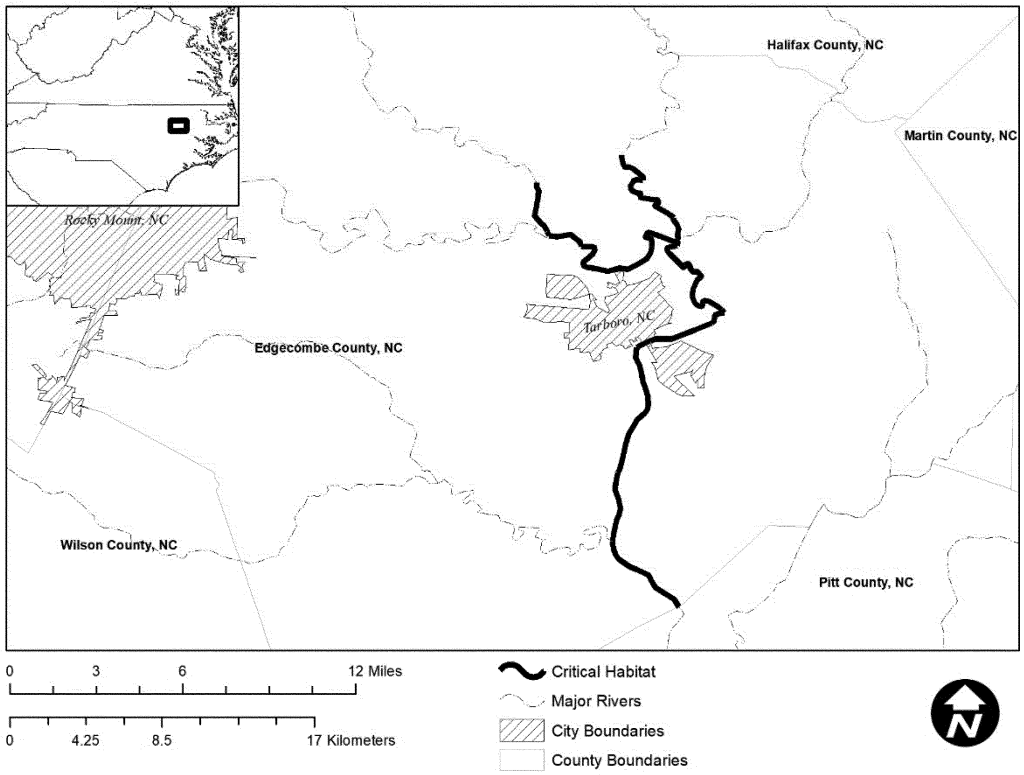


(17) Unit 12: TR4—Lower Tar River, Edgecombe and Pitt Counties, North Carolina.

(i) This unit consists of 30 river miles (48.3 river km) of the Lower Tar River, lower Swift Creek, and Fishing Creek in Edgecombe County, North Carolina, from NC97 near Leggett, North Carolina, to the Edgecombe County-Pitt County line near NC33.

(ii) Map of Unit 12 (Lower Tar River) follows:

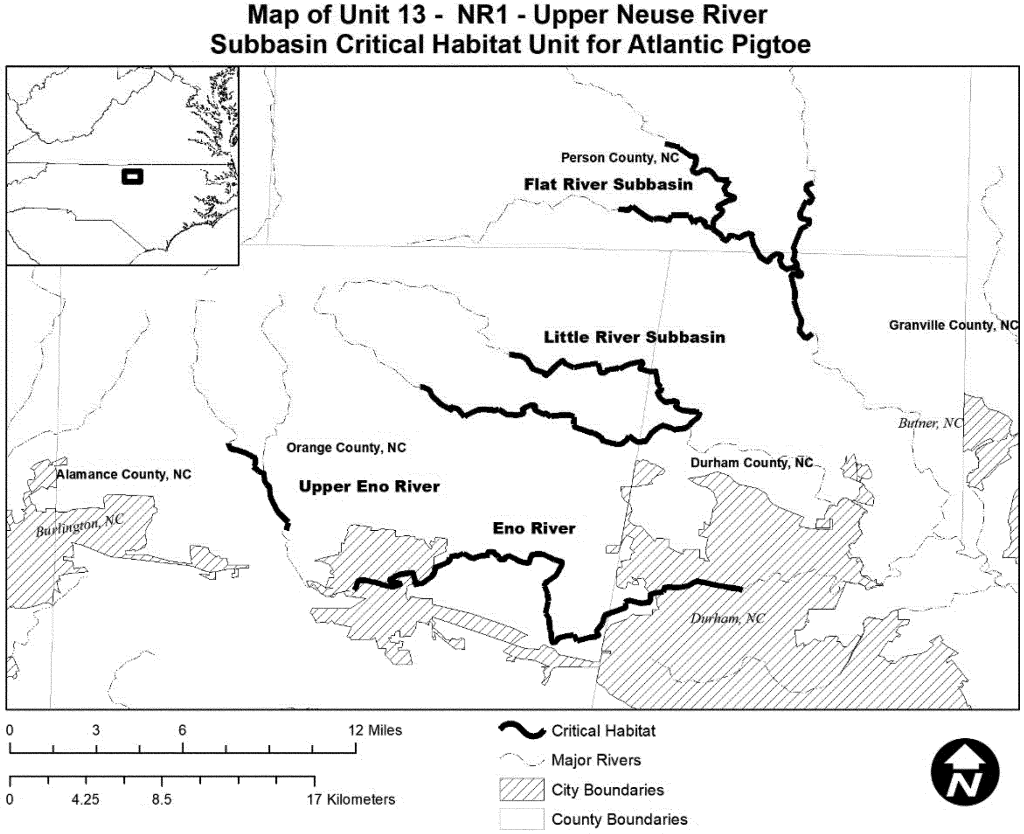
Map of Unit 12 - TR4 - Lower Tar River Critical Habitat Unit for Atlantic Pigtoe



(18) Unit 13: NR1—Upper Neuse River Subbasin, Person, Durham, and Orange Counties, North Carolina.

(i) This unit consists of 60 river miles (95 river km) in four reaches including Flat River, Little River, Eno River, and the Upper Eno River. The Flat River reach consists of 19 river miles (30.6 river km) in the Flat River Subbasin in Person and Durham Counties, North Carolina, including the South Flat River downstream of Dick Coleman Road, the North Flat River near Parsonage Road, and Deep Creek near Helena-Moriah Road downstream where each river converges into the Flat River downstream of State Forest Road. The Little River Subbasin includes 18 river miles (29 river km) of the North Fork and South Fork Little Rivers in Orange and Durham Counties, North Carolina. The Upper Eno River reach consists of 4 river miles (6.4 river km) in Orange County, North Carolina, including the West Fork Eno River upstream of Cedar Grove Road to the confluence with McGowan Creek. The Eno River reach consists of 18 river miles (29 river km) in Orange and Durham Counties, North Carolina, from below Eno Mountain Road to NC15–501.

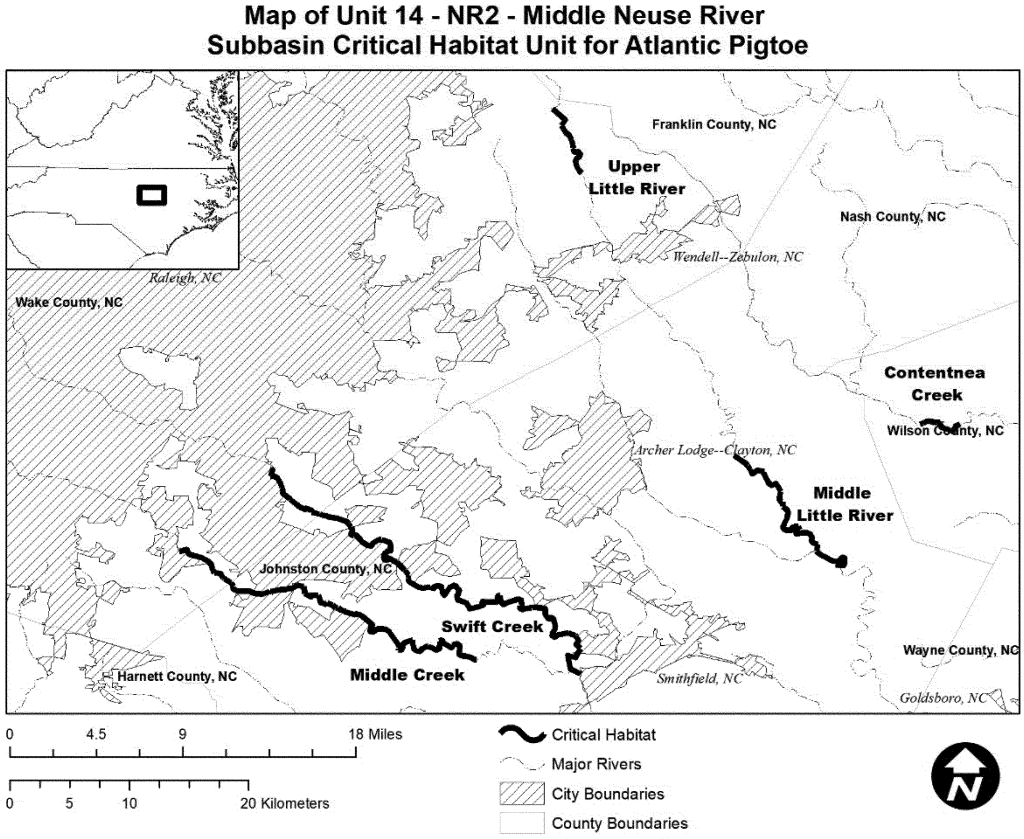
(ii) Map of Unit 13 (Upper Neuse River Subbasin) follows:



(19) Unit 14: NR2—Middle Neuse River Subbasin, Wake, Johnston, and Wilson Counties, North Carolina.

(i) This unit consists of 61 river miles (98.2 river km) in five reaches including Swift Creek, Middle Creek, Upper Little River, Middle Little River, and Contentnea Creek, all in North Carolina. The Middle Creek reach is 19 river miles (30.6 river km) below Old Stage Road downstream to below Crantock Road, and the Swift Creek reach is 25 river miles (40.2 river km) from Lake Benson downstream to its confluence with the Neuse, both in Wake and Johnston Counties. The Upper Little River reach includes 4 river miles (6.4 river km) of the Upper Little River from the confluence with Perry Creek to Fowler Road in Wake County, North Carolina. The Middle Little River reach includes 11 river miles (17.7 river km) from Atkinsons Mill downstream to NC301 in Johnston County, North Carolina. The Contentnea Creek reach consists of 2 river miles (3.2 river km) below Buckhorn Reservoir to just below Sadie Road near NC581 in Wilson County, North Carolina.

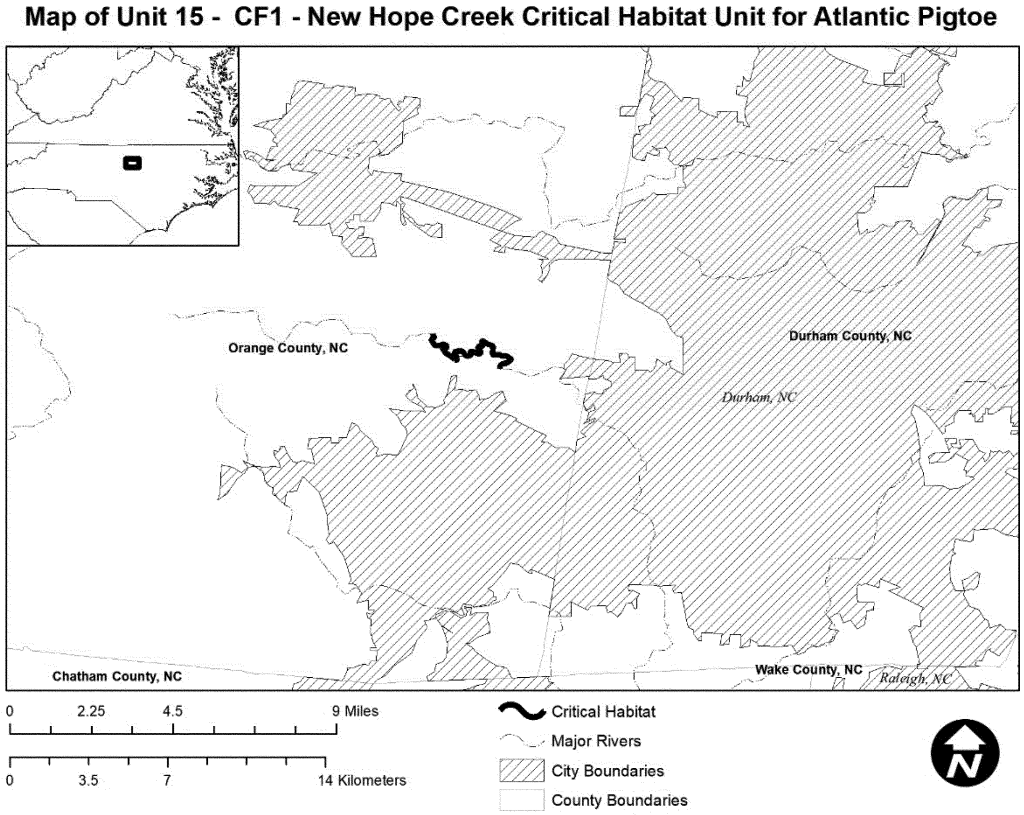
(ii) Map of Unit 14 (Middle Neuse River Subbasin) follows:



(20) Unit 15: CF1—New Hope Creek, Orange County, North Carolina.

(i) This unit consists of 4 river miles (6.4 river km) of habitat in the New Hope Creek from NC86 to Mimosa Road.

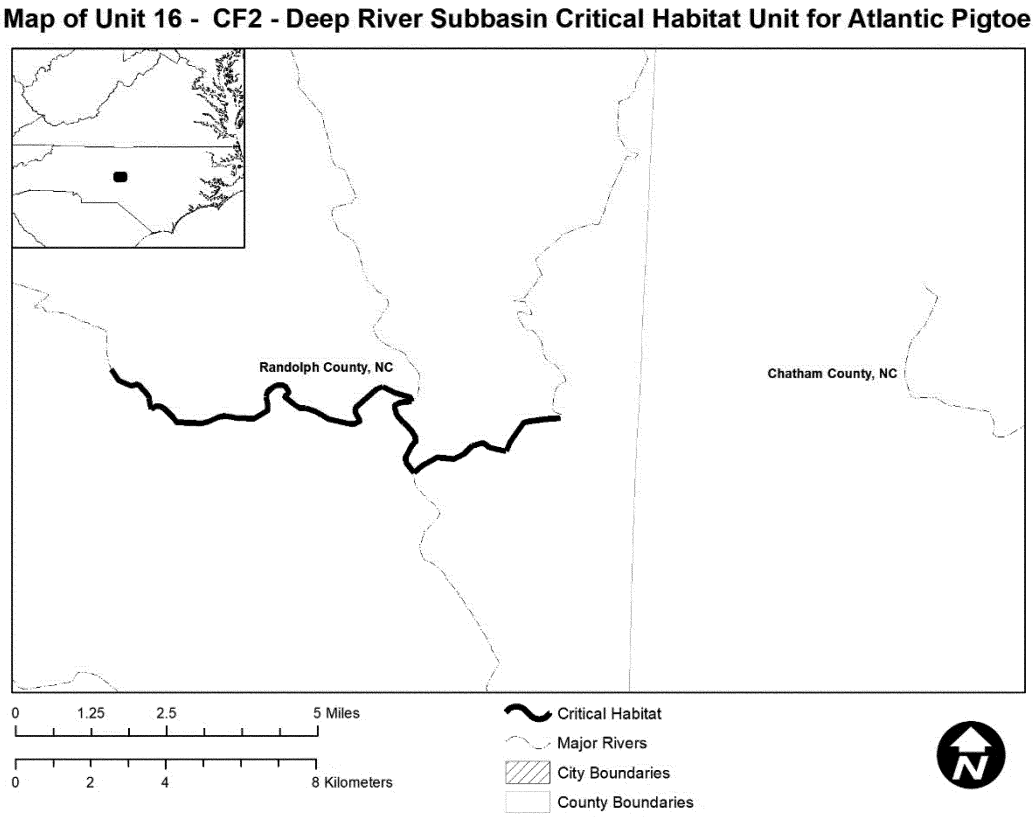
(ii) Map of Unit 15 (New Hope Creek) follows:



(21) Unit 16: CF2—Deep River Subbasin, Randolph County, North Carolina.

(i) The Deep River Subbasin unit consists of 10 river miles (16.1 river km), including the mainstem between Richland and Brush Creeks as well as Richland Creek from Little Beane Store Road to the confluence with the Deep River and Brush Creek from Brush Creek Road to the confluence with the Deep River.

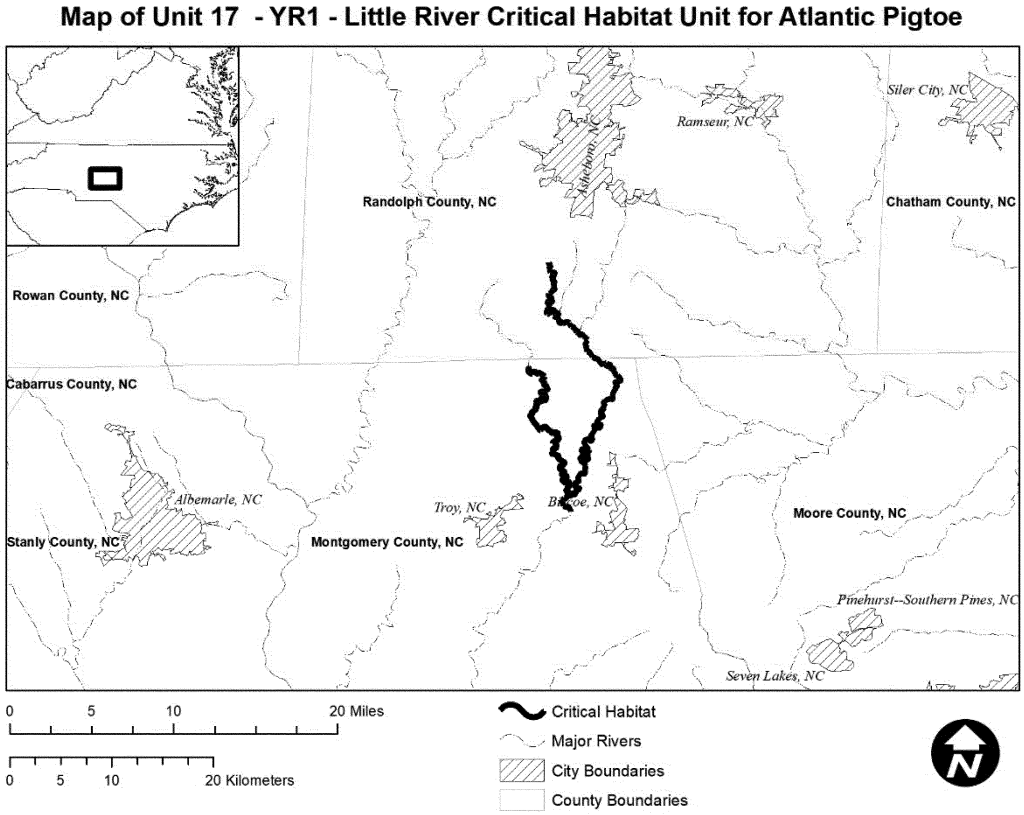
(ii) Map of Unit 16 (Deep River Subbasin) follows:



(22) Unit 17: YR1—Little River, Randolph and Montgomery Counties, North Carolina.

(i) This unit consists of 40 river miles (64.4 river km) of Little River from SR1114 downstream to Okeewemee Star Road, including the West Fork Little River from NC134 to the confluence with the Little River.

(ii) Map of Unit 17 (Little River) follows:



* * * * *

Martha Williams

Principal Deputy Director, Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2021–24784 Filed 11–15–21; 8:45 am]

BILLING CODE 4333–15–C

Reader Aids

Federal Register

Vol. 86, No. 218

Tuesday, November 16, 2021

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6050**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.govinfo.gov.**

Federal Register information and research tools, including Public Inspection List and electronic text are located at: **www.federalregister.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html and select** *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, NOVEMBER

60159–60356 1
60357–60530 2
60521–60748 3
60749–61042 4
61043–61664 5
61665–62080 8
62081–62464 9
62465–62712 10
62713–62892 12
62893–63306 15
63307–64054 16

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
10295 60531
10296 60533
10297 60535
10298 60537
10299 60539
10300 60541
10301 60543
10302 60545
10303 60547
10304 62893
10305 63303
Executive Orders:
14051 60747
Administrative Orders:
Memorandums:
Memorandum of October 29, 2021 60751
Notices:
Notice of October 28, 2021 60355
Notice of November 9, 2021 62709
Notice of November 9, 2021 62711
Notice of November 10, 2021 62891
Presidential Determinations:
Presidential Determination No. 2022–03 of October 22, 2021 60749

5 CFR

315 61043
330 61043
890 60357
2638 63307

6 CFR

5 61665

7 CFR

319 62465
1220 61668
1767 63308
4284 60753
Proposed Rules:
959 61718
980 61718

9 CFR

590 60549
Proposed Rules:
201 60779

10 CFR

Ch. I 62713
72 61047
Proposed Rules:
53 61718
72 61081
429 63318
430 ..... 60376, 60974
431 63318

12 CFR

1022 62468
1026 60357
Proposed Rules:
1240 60589

13 CFR

Proposed Rules:
121 60396
124 61670
125 61670
126 61670
127 61670

14 CFR

39 ..... 60159, 60162, 60364, 60550, 60554, 60557, 60560, 60563, 60753, 61053, 61056, 61058, 61060, 61063, 61673, 61676, 61679, 62714, 62717, 62719, 62895, 62898, 63308
61 62081
71 ..... 60165, 60367, 60756, 60757, 62721, 62723
95 62088
97 ..... 63311, 63312
107 62472
1215 60565
Proposed Rules:
39 ..... 60600, 61083, 61086, 61086, 61719, 62742, 62744, 62746, 62960, 63319, 63322
71 ..... 60183, 60185, 60186, 60416, 60418, 60421, 60423, 60781, 60783, 60784, 61722, 61724, 61728, 62749, 62750, 62753, 62755, 62756, 62758, 62760, 62761, 62962
121 60424

15 CFR

744 60759
922 62901
1500 63315

17 CFR

275 62473

21 CFR

510 61682
520 61682
522 61682
524 61682
556 61682
558 61682
1308 60761
Proposed Rules:
1308 60785

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. This list is also available online at *https://www.archives.gov/federal-register/laws*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available at *https://www.govinfo.gov*. Some laws may not yet be available.

H.R. 3684/P.L. 117–58
Infrastructure Investment and Jobs Act (Nov. 15, 2021; 135 Stat. 429)
Last List November 15, 2021

Public Laws Electronic Notification Service (PENS)

PENS is a free email notification service of newly enacted public laws. To subscribe, go to *https://listserv.gsa.gov/cgi-bin/wa.exe?SUBED1=PUBLAWS-L&A=1*

Note: This service is strictly for email notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.